Hailey's Hope Foundation's
Fifth Annual

Beach Bash

Cocktail & Dinner Reception
Manursing Island Club
Saturday, June 1, 2013

We've created a children's hospital that treats kids like their lives depend on it.

Maria Fareri Children's Hospital at Westchester Medical Center
congratulates the Hailey's Hope Foundation
for making a difference in the lives of NICU families.

At Maria Fareri Children's Hospital at Westchester Medical Center, we specialize in care that helps the whole family get better. We're making incredible advances in children's healthcare, so we'll be ready when your child needs us most.

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MEDICAL CENTER

Hailey's Hope Foundation's Fifth Annual

Beach Bash

Cocktail & Dinner Reception

to benefit families with premature and critically ill babies
in Neonatal Intensive Care Units (NICUs) at Maria Fareri
Children's Hospital and other New York area hospitals

Saturday, June 1, 2013
Manursing Island Club
Rye, New York

Premier Sponsors
Reckson, A Division of SL Green
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Evening Events

FOOD & DRINK
Premium Open Bar
Dinner

REMARKS
Donna Zion
Vice President of Hailey's Hope Foundation
Hailey's mom

GUEST SPEAKER
Dr. Amir Lahav
Lahav Lab for Neonatal Research
Brigham and Women's Hospital (Teaching Affiliate of Harvard Medical School)
Boston, Massachusetts

The Schlubach Family
A Hailey's Hope Foundation NICU family

AUCTION & RAFFLES

DESSERT & COFFEE

Good Evening!

Thank you for joining us tonight for Hailey's Hope Foundation's Fifth Annual *Beach Bash* Benefit. As we enjoy this evening, we have the joy of knowing that our efforts have brought hope, comfort and essential support to over 1,300 NICU families in need as they face and cope with the challenges of caring for their babies in the Neonatal Intensive Care Unit (NICU).

2013 has been a fantastic year for Hailey's Hope Foundation. We are proud to celebrate two significant milestones -- our 5-year anniversary with the Regional NICU (Level IV) at Maria Fareri Children's Hospital (at Westchester Medical Center) in Valhalla, and the distribution of support to Hailey's Hope Foundation's 1,000th family—The Bruno Family. We are also exited for the re-launch of Hailey's Hope Foundation's website in the beginning of June, which will prove to be an even greater resource for NICU families.

As more and more families are faced with the reality of having babies born prematurely and critically ill, the demand for Hailey's Hope Foundation's unique and essential support continues to grow. Among the 30-40 applications for assistance we receive each month, no family has been denied support. Additionally, we have been able to extend our reach to assist NICU families at New York Presbyterian/Morgan Stanley Children's Hospital (NYC), Blythedale Children's Hospital (Westchester County), and St. Luke's Hospital (Orange County). We have made tremendous progress, yet there is still much more to be done. Your support this evening will bring us closer to our goals to fulfill the financial, emotional and educational needs of NICU families and to help improve the quality of NICU care. Together, we can give every NICU baby and family a greater fighting chance!

It is truly inspiring to see the generosity of family, friends and supporters who have helped us raise over $650,000 since we formed in December 2007. We will continue to work hard to be a valuable support system for NICU families during this critical time.

Thank you for your generosity this evening. We are deeply grateful to you and look forward to your continued support.

Yours truly,

Jeffrey Randazzo
President

Beach Bash Committee

Co-Chairs
Donna Zion
Doreen Zion

Committee
Debra Randazzo, Ann Siegel, Dawn Singer,
Marvin Siegel, Suzanne Decina

"No one can do everything, but everyone can do something"
— Author Unknown

Dear Friends:

Thank you for joining us on this special evening to celebrate the great accomplishments of Hailey's Hope Foundation in helping NICU families and their babies.

The outpouring of support for this year's event is incredibly moving and inspiring. We want to express our sincere appreciation for the support of our *Premier Sponsors*: Reckson, a Division of SL Green, Lincoln Land Services, LLC and Jones Lang LaSalle; our *Participating Sponsors*: The DiLiberto Family, The Holliday Foundation, Tina and Andrew Mathias, Securitas Security Services, USA, Inc.; our *Entertainment Sponsors*: The Popper Family and The Galiano Family; our *Dessert Sponsor*: Palotta Landscaping, Inc.; and our *Guest Gifts Sponsors*: Advanced Control Solutions and Davis Disposal Service, Inc. We are grateful to all of our very generous donors for making tonight a great success, including businesses and families who donated wonderful items to our Auction and Raffle, purchased tickets, and purchased advertisements in our Online Reception Journal.

This evening would not be as memorable an event without the hard work, creativity and commitment of our Beach Bash Committee. Thank you for everything. We would also like to thank Lisa Guinta for the beautiful design of our Online Reception Journal and Manursing Island Club for the beautiful setting and wonderful food and service.

On behalf of Hailey's Hope Foundation and the Committee, thank you for your continued support.

Enjoy!

Warm regards,
Donna Zion and Doreen Zion
Co-Chairs

Hailey's Hope Foundation
wishes to thank the following donors for their generous support

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List as of 5/21

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AT WESTCHESTER MEDICAL CENTER

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(914) 493-8558

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Hailey's Hope Foundation

For Outstanding Achievements in Health Care and Philanthropy

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Our NICU Graduates

MATTHEW RANDAZZO

Born: 28 weeks at
2 lbs. 8 oz.

NICU stay:
62 days

JEFFREY RANDAZZO

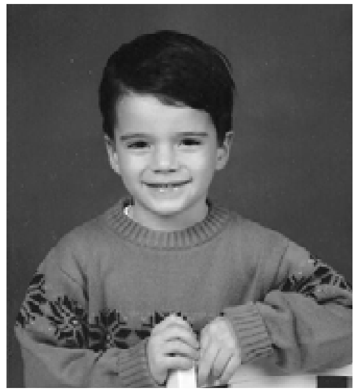
Born: 38 weeks
at 7 lbs. 14 oz.

NICU stay:
1 day

DYLAN RANDAZZO

Born: 33 weeks
at 4 lbs. 5 oz.

NICU stay:
21 days



TAYLOR DECINA

Born: 40 weeks
at 8 lbs. 1 oz.

NICU stay:
4 days

ALENCE ZION

Born: 30 weeks at
2 lbs. 15 oz.

NICU stay:
42 days

JAKE ZION

Born: 32 weeks
at 3 lbs. 8 oz.

NICU stay:
28 days

KADEN ZION

Born: 34 weeks
at 4 lbs. 6 oz.

NICU stay:
10 days

MADISON DECINA

Born: 36 weeks
at 5 lbs. 15 oz.

NICU stay:
14 days

Hailey's Hope Foundation

Hailey's Hope Foundation supports families with premature and critically ill babies in New York-area NICUs (Neonatal Intensive Care Units) and improves the quality of NICU care so these babies can have the best possible beginnings in life. When babies are born too early, too small, or very sick, it is crucial for their families to be involved in their care as much as possible. However, many are unprepared for the emotional and financial challenges of a NICU hospitalization. Parents often fear the unknown and struggle to cope with the demands of daily life (i.e., work, home and childcare), not to mention exhausting NICU visits and commutes. By providing financial assistance, emotional support, and educational information, we help NICU families manage this difficult time and become their baby's best advocate. We also fund clinical neonatal research and work closely with NICUs to help give more babies a greater fighting chance.

As a grassroots, volunteer-based, 501(c)(3) nonprofit organization, we carry out our mission through targeted programs and initiatives:

- **Financial Assistance:** A NICU stay can last weeks or months, and the additional expenses can quickly become a serious hardship, especially for economically strained families. We help families in need with non-medical expenses, from lodging and transportation to breast pump rentals and meals, so they can spend as much time as possible at the hospital with their baby and NICU team.
- **Education & Resources:** Families can use our website (www.haileyshopefoundation.org) to access educational information, neonatal research and other resources, including a growing community of NICU parents who share their experience. Our longer-term goals include developing in-hospital NICU family resource centers and parent support groups.
- **Specialized Care Packages:** Leaving the highly specialized, 24-hour care of NICU doctors and nurses is daunting for any parent. At discharge, we supply families with care packages to help ease the anxiety of transitioning home with their tiny miracles. Our packages contain baby care items, supplies and important information about post-NICU issues, including local resources for early intervention.
- **Partnership With NICUs:** We work closely with NICU doctors, nurses and social workers to help them improve care. They know better than anyone where support is needed, whether it's breastfeeding advocacy, medical supplies or specialized equipment. The NICU nursing staff is on the front lines everyday and helps us target our efforts to what families and babies need most.

Hailey's Hope Foundation was created in December 2007 by four couples that endured many NICU crises together and saw first hand the startling void in family support during one of the most difficult times in their lives. We are working hard to be a valuable resource for NICU families, to give a voice to their needs, and to make their NICU paths a little easier to walk. Currently we are partnered with The Regional Neonatal Center at Maria Fareri Children's Hospital (Westchester Medical Center) and the new Rowley Birthing Center at Orange Regional Medical Center. Additionally, we have provided support to NICU families at New York-Presbyterian Morgan Stanley Children's Hospital, Blythedale Children's Hospital, and St. Luke's Cornwall Hospital. To date, we have raised over $650,000, provided support to over 1,300 NICU families, and purchased essential medical equipment and supplies for the NICU.

Hailey's Hope Foundation was created in loving memory of our little angel, Hailey, the daughter of Board members, Isaac and Donna Zion, who was born prematurely and passed away shortly after birth in 2003.

Thank you ...

Dear Hailey's Hope Foundation:

"Thank you so much for helping us during our daughter's NICU stay. The gratitude we feel cannot be put into words. Your thoughtfulness really touched our hearts. What a wonderful foundation. We are forever grateful for all of the support you gave us to use, with being 5 hours away from home and starting a new family. Thank you again."
The Perry Family, Barre, VT

"We just wanted to say the biggest Thank You to all of you. You have helped us so much with support and we will always be grateful. You have definitely made a challenging time easier for us. Thank you very much. Thank you also for the camera on Mother's Day. We took a lot of special family photos. That was so nice of you."
The Ryan Family, Harriman, NY

"We greatly appreciate the support you gave us at Maria Fareri Children's Hospital back in April. It was a ray of sunshine and hope during a very difficult time when our twin boys were in the NICU. We are blessed to have them both home with us now. We are very grateful for your help."
The Rosenberg Family,
Cortlandt Manor, NY

"My family and I would like to thank you for your assistance while our girls were in the NICU at Maria Fareri Children's Hospital. Our twin girls were born at 32 weeks due to a high-risk pregnancy. Your support, understanding and caring during such a stressful time was GREATLY appreciated. Thank you for being there for my family and others."
The De Luccia Family,
Pound Ridge, NY

"We just wanted to extend a note of thanks for the generous support you have provided our family with so far with the recent birth of our triplets and their NICU stay. We are so grateful for the support and amazed by the generosity of your foundation."
The Marr Family, Goshen, NY

"I wanted to write you a sincere note of thanks for your generous support for my husband and I as we stayed at the Ronald McDonald House to be closer to our baby. We feel so grateful to have received your support for lodging, transportation back and forth to the hospital and help with parking. It was a great help."
The Evangelista Family, West Point, NY

The Schlubach Family... Their NICU Story

On June 26, 2012, our lives changed forever. It was the day my wife and I joined the club nobody wants to join - the preemie parents club. The day prior, I got a call from my neighbor saying, "Max, you need to come home right now. There's an ambulance out front, and Sara is really upset. Not sure what's going on - but come home." That is how our journey began - a journey of worry, a journey of fear... but most importantly, a journey of hope.

I immediately called my wife, Sara, but she couldn't answer her phone because she was in the ambulance. Frankly, I don't remember much between the calls and arriving at Westchester Medical Center to find Sara, still pregnant, in Labor and Delivery. Her due date was October 11th. She was only 24 weeks, 4 days along. Sara had experienced some difficulties during the pregnancy - I remember her OBGYN had told us a few weeks earlier "the most important thing is to make it to 28 weeks. Miracles happen at 28 weeks." But she wasn't there yet. I was wondering if miracles still happened at 24 weeks.

The NICU doctor tried to prepare us for what to expect in the delivery room, but I was in denial. The doctors said to expect a lot of tubes, which didn't mean a lot to me until we were rushed to the delivery room - I never thought, in a million years, that the baby would actually come. I thought micro preemies were just something you saw on the discovery channel.

Our miracle - Lilliana Hope Schlubach, Lily, was born on June 26th, weighing 1 pound 12 ounces. I wore flip-flops into the delivery room, if that gives you any sense for how well prepared I was for this. Lily's birth hit me and my wife like a freight train. It ran us over. Then it backed up, and ran us over again, and again, and again. After delivery by cesarean, Lily was whisked off to the NICU before we could see her. The doctors said we could go see her in 45 minutes, once she was stabilized. An hour passed, then two hours. It felt like an eternity. We finally got to see her in the NICU and they told us they had a hard time stabilizing her--she was very sick. We could touch her, but not move our hands across her skin since it was about as thick as tissue paper. When I first saw Lily, it was very hard to process. She was so small and her skin was dark since her blood oxygen was so low. She was on an oscillating ventilator, she had an umbilical IV and a regular IV. The oscillating ventilator made her chest jiggle unnaturally- like humming bird breaths - but it kept her alive, and it kept her breathing. Seeing Lily for the first time was very difficult for Sara and me. We sat with her as her doctors tried to prepare us for the NICU journey we were about to begin. It would be scary, it would be the most difficult and heart wrenching period of our lives. Boy were they right. The doctors told us Lily had a 50% of survival, and if she did survive, an 80% chance of developmental delays. I told myself Lily isn't a statistic, she is a fighter.

I stayed in the hospital with Sara for the first few days. We were so scared and upset that we barely talked. These were the darkest days of our lives. Day four was when I discovered and embraced hope. Sara was still in the hospital and it was the first day I slept at home. That night, after spending the day at the hospital, I sat out under the stars in the backyard. It was a warm, clear summer night. I was a wreck, but, I decided that I would choose HOPE as the path that I was going the follow, and as the path I would try to lead my family down with me. Hope. Hope. Hope.

The Schlubach Family... Their NICU Story continued

I kept a blog of my daughter's battle for her life http://prayingforlily.blogspot.com. Every day, I would update the day's events, medications, or procedures. Lily spent 100 days in the NICU fighting for her life. She received almost a dozen blood transfusions, a platelet transfusion, two rounds of surfactant treatments, several rounds of antibiotics, a PIC line, three brain ultrasounds, a dozen x-rays, countless other procedures. And she won the fight!

The cause of her prematurity was a placental abruption, the underlying cause of which we never learned. Lily was born very, very sick. She had presumed sepsis and bronchopulmonary dysplasia, but thank God she had no brain bleeds. Early on she struggled with her red and white blood cell count balance, blood acidity and sodium levels her biggest issues were her lungs. Since she was born too early to have naturally developed surfactant, her lungs collapsed (in part and in whole) several times despite the administration of artificial surfactant. Lily showed some improvement, though, and at about 20 days of life she made it off of the oscillating ventilator and onto the standard ventilator. Then, she developed pneumonia, her lungs collapsed again, and the attending physician told us that she was "now the sickest baby in this NICU. We are back to day one. This came right about the time when we though she had made it past the worst of things.

We were scared before, but at this point we were terrified. Sara and I really thought Lily was going to die. The emptiness had come back - after three weeks of progress, we were back to day one. Lily was on the highest settings for the ventilator. There was nothing else they could do - "this is now her fight", the attending told us. Over the course of the next few days, by miracle and her guardian angels, Lily was able to fight off the pneumonia with two antibiotics. For the second time, the miracle workers saved her life! She began to progress again. Eating a little more, gaining an ounce here and there. The next several weeks were filled with apneas and bradycardias (episodes where your child stops breathing for 15 to 30 seconds at a time, and has to be medically revived, sometimes with a breathing bag). Scary would be an understatement.

Around late July, Lily made it off of the mechanical ventilator, on to CPAP, back onto the ventilator, then back onto the CPAP. What a roller coaster it was. Imagine thinking your child is going to die, then 5 days later thinking she will live, then 2 days later being told there is a chance she might not make it. That's what being a micropreemie parent is like. Counting the O's (ventilator settings) - counting ounces, those precious ounces - grow Lily, grow! Eat Lily, eat!

At about 90 days of life, Lily made it off of CPAP and onto the nasal cannula. She then progressed at a remarkable pace - and at 100 days of life, we brought her home. What a happy day! Easily one of the happiest days I can remember.

Since her discharge, things have been going well for Lily. She is now 15 pounds and her big sister, Addie, has developed an amazing bond with her. Lily has hit ALL of her adjusted-age developmental milestones - she can hear, she can see, she can track objects, she can smile and laugh and she can grab her toes and roll over - she is a miracle in every sense! There are some muscular tone issues we are watching closely, and we are addressing through physical therapy - PT twice a week, and water therapy every other week.

It seems to be working - her legs are much looser, but we are still working on her trunk and back tightness. Lily also has something called benign external hydrocephalus, which is excess cerebrospinal fluid between the brain and cranium. It typically self-resolves by the age of 2 or 3, so we are hopeful there won't be any lasting effects. At this point, Lily has defied EVERY odd, defied EVERY statistic. She's been through it all - she's fought (and won) every fight. She's a strong, determined kid. She can do anything she sets her mind to!

Raising a preemie isn't anything someone ever plans on. It starts out scary, even terrifying - and every outcome is different. My wife and I - our whole family - have so, so much to be thankful for. Lily is truly a miracle. Looking at her, you'd never know she was born four months early. She's amazing! She had the best medical care - everyone at the Maria Fareri NICU was just awesome. Two doctors in particular, Dr Alpin and Dr Uduak, played huge roles in saving Lily's life. The NICU nurses, all of them, were nothing short of miracle workers.

Sara and I were fortunate to have an amazing support network - our family, our friends, even strangers helped us through it - from things like dinners, to babysitting, or even just giving us an open ear to talk. Because of my blog, people from all over the world let us know we were in their thoughts - and thousands of people all over the world were Praying for Lily. The support of strangers during a time like that was touching, and amazing. It helped keep my wife and me going.

Hailey's Hope Foundation helped us out throughout Lily's NICU stay - I can't thank the donors and everyone at HHF enough. Donors should know that their generosity directly impacts the lives of local parents, and helps them through the most difficult period of their lives. Thank you!

Latest Fundraisers and Activities

Inaugural Golf Outing

The Golf Club of Purchase, Purchase

Spectacular! Picture Perfect! Amazing! Just a few of the words guests used to describe Hailey's Hope Foundation's 1st Annual Golf Outing held on Monday, October 1, 2012 at the exclusive Golf Club of Purchase (Purchase, NY). The outing was a great success and raised over $60,000 for our programs that provide financial, emotional and informational support to NICU families and improve the quality of NICU care.

We are very grateful to our event sponsors, Alliance Building Services (Title Sponsor), Au Bon Pain (Lunch Sponsor) and Fried Frank (Lunch Sponsor), all of our Hole sponsors, our golfers, our gift bag donors, our volunteers and the incredible staff at the Golf Club of Purchase for their generosity and for making our first charity golf outing a truly memorable event.

Latest Fundraisers and Activities

Fiesta!

Harness Racing Museum, Goshen

Many friends and supporters came out to join Hailey's Hope Foundation at its Fiesta Dinner Auction Fundraiser at Harness Racing Museum in Goshen, New York on September 8, 2012. Sponsored by Delancey's Bar and Restaurant, it was a fun and memorable evening. Proceeds benefitted NICU families at Orange Regional Medical Center, Maria Fareri Children's Hospital, and other New York area hospitals.

Beach Bash

Manursing Island Club, Rye

On June 2, 2012, Hailey's Hope Foundation hosted its 4th Annual "*Beach Bash*" Benefit at Manursing Island Club in Rye. Over 125 guests enjoyed cocktails, dinner, fun raffles, and a marshmallow roast on a gorgeous night under the stars overlooking the Long Island Sound. The event was a great success and raised $75,000 for its programs and initiatives that support the needs of families struggling to cope with their baby's NICU hospitalization. HHF was proud to present longtime Westchester residents and philanthropists, Olivia and Lawrence Blau, with the 2012 Hailey Zion Memorial Award for Community Spirit in recognition of their extraordinary commitment to helping the NICU community. The event was sponsored by *Premier Sponsors:* Reckson, a Division of SL Green and Lincoln Land Services LLC; *Participating Sponsors:* The DiLiberto Family, The Holliday Foundation, and Andrew and Tina Mathias, and *Dessert Sponsor*: The Galiano Family.

WE PROUDLY SALUTE

THE HAILEY'S HOPE FOUNDATION

for their exceptional work and generosity

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Lincoln Land Services LLC proudly supports

HAILEY'S HOPE FOUNDATION

in their continued efforts to assist,
support and comfort NICU families.

We wish you continued success.

Chris Hein - Drew Melchionni - Vincent Ponte

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TRANSACTION MANAGEMENT EXPERTS

SEVERE RSV* DISEASE STILL HAPPENS

*RSV = respiratory syncytial virus

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

IDENTIFYING CHILDREN AT HIGH-RISK† MAY BE KEY TO HELPING PROTECT THEM FROM SEVERE RSV DISEASE

†Safety and efficacy of Synagis® were established in children at high risk of RSV disease: children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (≤35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD).

SYNAGIS®
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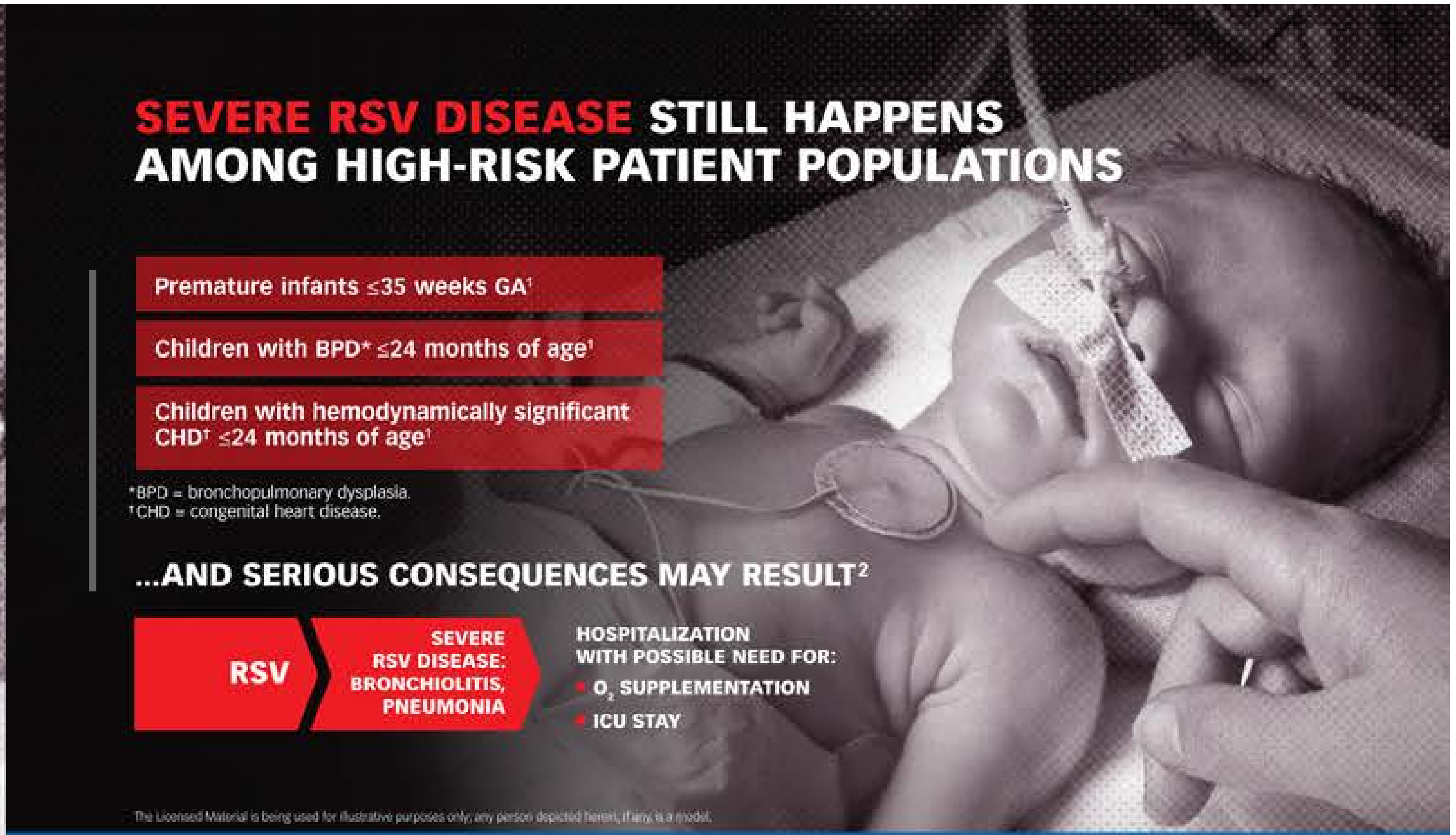
SELECT SAFETY INFORMATION

Synagis is contraindicated in children who have had a previous significant hypersensitivity reaction to Synagis. Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to Synagis. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to Synagis.

Please see Important Safety Information on next page and accompanying Brief Summary of Prescribing Information for Synagis.



SEVERE RSV DISEASE STILL HAPPENS AMONG HIGH-RISK PATIENT POPULATIONS

- Premature infants ≤35 weeks GA[1]
- Children with BPD* ≤24 months of age[1]
- Children with hemodynamically significant CHD† ≤24 months of age[1]

*BPD = bronchopulmonary dysplasia.
†CHD = congenital heart disease.

...AND SERIOUS CONSEQUENCES MAY RESULT[2]

RSV → SEVERE RSV DISEASE: BRONCHIOLITIS, PNEUMONIA → HOSPITALIZATION WITH POSSIBLE NEED FOR:

- O_2 SUPPLEMENTATION
- ICU STAY

IT'S IN YOUR POWER TO HELP PREVENT HOSPITALIZATIONS WITH SEVERE RSV DISEASE IN HIGH-RISK PATIENTS

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IMPORTANT SAFETY INFORMATION

Synagis® (palivizumab) is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (≤35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD). The recommended dose of Synagis is 15 mg/kg of body weight given monthly by intramuscular injection. The first dose of Synagis should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season.

The efficacy of Synagis at doses less than 15 mg/kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

Synagis is contraindicated in children who have had a previous significant hypersensitivity reaction to Synagis. Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to Synagis. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to Synagis. The relationship between these reactions and the development of antibodies to Synagis is unknown. If a significant hypersensitivity reaction occurs with Synagis, its use should be permanently discontinued. If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of Synagis. As with any intramuscular injection, Synagis should be given with caution to children with thrombocytopenia or any coagulation disorder. Palivizumab may interfere with immunological-based RSV diagnostic tests, such as some antigen detection-based assays.

Adverse reactions occurring greater than or equal to 10% and at least 1% more frequently than placebo are fever and rash. In post-marketing reports, cases of severe thrombocytopenia (platelet count <50,000/microliter) and injection site reactions have been reported.

Please see accompanying Brief Summary of Prescribing Information for Synagis.

References: 1. Synagis [package insert]. Gaithersburg, MD: MedImmune. **2.** Collins PL, Crowe JE Jr. Respiratory syncytial virus and metapneumovirus. In: Knipe DM, Howley PM, eds. *Fields Virology.* 5th ed. Philadelphia, PA: Lippincott Williams and Wilkins; 2007:1601–1646.

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Brief Summary of Prescribing Information
SYNAGIS® (PALIVIZUMAB)
for Intramuscular Administration **Rx only**

INDICATIONS AND USAGE

Synagis is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (less than or equal to 35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD).

The following point should be considered when prescribing Synagis:

- The safety and efficacy of Synagis have not been established for treatment of RSV disease.

DOSAGE AND ADMINISTRATION

Dosing Information

The recommended dose of Synagis is 15 mg per kg of body weight given monthly by intramuscular injection. The first dose of Synagis should be administered prior to commencement of the RSV season and the remaining doses should be administered monthly throughout the RSV season. Children who develop an RSV infection should continue to receive monthly doses throughout the RSV season. In the northern hemisphere, the RSV season typically commences in November and lasts through April, but it may begin earlier or persist later in certain communities.

Synagis serum levels are decreased after cardio-pulmonary bypass. Children undergoing cardio-pulmonary bypass should receive an additional dose of Synagis as soon as possible after the cardio-pulmonary bypass procedure (even if sooner than a month from the previous dose). Thereafter, doses should be administered monthly as scheduled.

The efficacy of Synagis at doses less than 15 mg per kg, or of dosing less frequently than monthly throughout the RSV season, has not been established.

CONTRAINDICATIONS

Synagis is contraindicated in children who have had a previous significant hypersensitivity reaction to Synagis.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Cases of anaphylaxis and anaphylactic shock, including fatal cases, have been reported following initial exposure or re-exposure to Synagis. Other acute hypersensitivity reactions, which may be severe, have also been reported on initial exposure or re-exposure to Synagis. Signs and symptoms may include urticaria, pruritus, angioedema, dyspnea, respiratory failure, cyanosis, hypotonia, hypotension, and unresponsiveness. The relationship between these reactions and the development of antibodies to Synagis is unknown. If a significant hypersensitivity reaction occurs with Synagis, its use should be permanently discontinued. **If anaphylaxis or other significant hypersensitivity reaction occurs, administer appropriate medications (e.g., epinephrine) and provide supportive care as required.** If a mild hypersensitivity reaction occurs, clinical judgment should be used regarding cautious readministration of Synagis.

Coagulation Disorders

Synagis is for intramuscular use only. As with any intramuscular injection, Synagis should be given with caution to children with thrombocytopenia or any coagulation disorder.

RSV Diagnostic Test Interference

Palivizumab may interfere with immunological-based RSV diagnostic tests such as some antigen detection-based assays. In addition, palivizumab inhibits virus replication in cell culture, and therefore may also interfere with viral culture assays. Palivizumab does not interfere with reverse transcriptase-polymerase chain reaction based assays. Assay interference could lead to false-negative RSV diagnostic test results. Therefore, diagnostic test results, when obtained, should be used in conjunction with clinical findings to guide medical decisions.

Treatment of RSV Disease

The safety and efficacy of Synagis have not been established for treatment of RSV disease.

Proper Administration

The single-dose vial of Synagis does not contain a preservative. Administration of Synagis should occur immediately after dose withdrawal from the vial. The vial should not be re-entered. Discard any unused portion.

ADVERSE REACTIONS

The most serious adverse reactions occurring with Synagis are anaphylaxis and other acute hypersensitivity reactions.

Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to Synagis (n=1639) compared with placebo (n=1143) in children 3 days to 24.1 months of age at high risk of RSV-related hospitalization in two clinical trials. Trial 1 was conducted during a single RSV season and studied a total of 1502 children less than or equal to 24 months of age with BPD or infants with premature birth (less than or equal to 35 weeks gestation) who were less than or equal to 6 months of age at study entry. Trial 2 was conducted over four consecutive seasons among a total of 1287 children less than or equal to 24 months of age with hemodynamically significant congenital heart disease.

In Trials 1 and 2 combined, fever and rash were each reported more frequently among Synagis than placebo recipients, 27% versus 25%, and 12% versus 10%, respectively. Adverse reactions observed in the 153-patient crossover study comparing the liquid and lyophilized formulations were comparable for the two formulations, and were similar to those observed with Synagis in Trials 1 and 2.

Immunogenicity

In Trial 1, the incidence of anti-palivizumab antibody following the fourth injection was 1.1% in the placebo group and 0.7% in the Synagis group. In children receiving Synagis for a second season, one of the fifty-six children had transient, low titer reactivity. This reactivity was not associated with adverse events or alteration in serum concentrations. Immunogenicity was not assessed in Trial 2.

A trial of high-risk preterm children less than or equal to 24 months of age was conducted to evaluate the immunogenicity of the lyophilized formulation of Synagis (used in Trials 1 and 2 above) and the liquid formulation of Synagis. Three hundred seventy-nine children contributed to the 4 to 6 months post-final dose analysis. The rate of anti-palivizumab antibodies at this time point was low in both formulation groups (anti-palivizumab antibodies were not detected in any subject in the liquid formulation group and were detected in one subject in the lyophilized group (0.5%), with an overall rate of 0.3% for both treatment groups combined).

These data reflect the percentage of children whose test results were considered positive for antibodies to palivizumab in an enzyme-linked immunosorbent assay (ELISA) and are highly dependent on the sensitivity and specificity of the assay.

The ELISA has substantial limitations in detecting anti-palivizumab antibodies in the presence of palivizumab. Immunogenicity samples tested with the ELISA assay likely contained palivizumab at levels that may interfere with the detection of anti-palivizumab antibodies.

An electrochemical luminescence (ECL) based immunogenicity assay, with a higher tolerance for palivizumab presence compared to the ELISA, was used to evaluate the presence of anti-palivizumab antibodies in subject samples from two additional clinical trials. The rates of anti-palivizumab antibody positive results in these trials were 1.1% and 1.5%.

Postmarketing Experience

The following adverse reactions have been identified during post approval use of Synagis. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and Lymphatic System Disorders: severe thrombocytopenia (platelet count less than 50,000 per microliter)

General Disorders and Administration Site Conditions: injection site reactions

Limited information from post-marketing reports suggests that, within a single RSV season, adverse events after a sixth or greater dose of Synagis are similar in character and frequency to those after the initial five doses.

DRUG INTERACTIONS

No formal drug-drug interaction studies were conducted. In Trial 1, the proportions of children in the placebo and Synagis groups who received routine childhood vaccines, influenza vaccine, bronchodilators, or corticosteroids were similar and no incremental increase in adverse reactions was observed among children receiving these agents.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C: Synagis is not indicated for adult usage. It is not known whether Synagis can cause fetal harm or could affect reproductive capacity when administered to a pregnant woman.

Animal Data

Animal reproduction studies have not been conducted.

Pediatric Use

The safety and effectiveness of Synagis in children greater than 24 months of age at the start of dosing have not been established.

OVERDOSAGE

Overdoses with doses up to 70 mg per kg have been reported in clinical studies and post-marketing experience with Synagis, and in some cases, adverse reactions were reported. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment instituted.

PATIENT COUNSELING INFORMATION

The healthcare provider should discuss the potential benefits and risks of Synagis with the parents or guardians of Synagis recipients. Parents or guardians should be informed of the possible side effects of Synagis and of the signs and symptoms of potential allergic reactions and should be advised of the appropriate actions. Parents or guardians should understand the dosing schedule and the importance of compliance with the full course of therapy.

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Revision Date: April 2012

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In honor of our daughter, Katherine, for her time spent and the thoughtful care given to her in the Pediatric Cardiac Intensive Care Unit at Morgan Stanley Children's Hospital when she was six months old.

- Karen and Nate Ebeling

Congratulations to Hailey's Hope Foundation on your tremendous efforts to help NICU families and babies in need

ANTHONY J. MANZIANO, CPA, MST LLC
Certified Public Accountant & Consultant

509 Kings Court
Woodbridge, New Jersey 07095
Phone: 732-610-3159
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To our special angel, Hailey:

Even though you are not here to play with us, we know you are in heaven playing with the angels and smiling down on us.

We love you and miss you everyday.

Thank you for keeping us safe.

Love,

Alence, Jake, Kaden, Matthew, Jeffrey, Dylan,
Taylor, JD, Maddie, Amber, Kaitlyn & Leah