OCTOBER 2018

NEWSLETTER – VOL. X

CONTENTS

INAUGURAL APPROVALS FOR RNA-BASED MEDICINE

In the case of another historic first in the world of healthcare, this summer saw the first US and EU regulatory approvals for an RNA interference (RNAi) therapeutic, in the form of Alnylam's Onpattro (patisiran). The drug, given as an infusion, was approved to treat polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adult patients. A rare and often fatal disease, hAATR is characterized by the buildup of abnormal amyloid protein in peripheral nerves, the heart, and other organs. Up until this approval, the American College of Cardiology's recommendations for treatment were merely supportive care and clinical trials, pointing to the level of unmet need for this patient population[1].

Still, it has been anything but smooth sailing for Onpattro, nor for the field of RNA-based medicines. Like gene therapy, it has seen an earlier wave of enthusiasm come crashing down in the wake of technical challenges and safety issues. While Onpattro will not be a panacea to all the known issues, it is important to note where and how it has succeeded where others have failed and to understand what it means for other candidates in the pipeline.

HOW IT WORKS

To understand how RNAi works, transport yourself to your high school biology class where you learned about the "central dogma" theory that explains the relationship between DNA, RNA and proteins – that DNA in the nucleus forms genes which are the template for transcription to RNA, which in turn is the template for translation to proteins. Those proteins then serve as a central player in most biological systems. In individuals without hAATR, the liver produces the TTR protein, used to transport vitamin A and a thyroid-binding protein in the body. Patients with hATTR have a mutation in the gene for TTR, which leads to the creation of a defective and unstable TTR protein. Onpattro binds to the mutated mRNA sequence that causes the defective protein, and cuts out that sequence, effectively halting the production of the misfolded and defective protein[2]. Of note, this approach targets the upstream cause of the defect, and not simply the downstream symptoms that are the manifestation of the defect.

LOCATION, LOCATION, LOCATION

RNAi does not simply work by targeting the mutated mRNA of interest – it must additionally be specifically targeted to the tissue(s) of interest, which is the tougher nut to crack. The liver, the target organ of interest in hATTR, happens to be better suited for targeted drug delivery given its unique vasculature – notably that it has both the hepatic artery and hepatic vein, allowing it to effectively double dip on whatever has been infused into the blood stream, compared

[1] http://blogs.sciencemag.org/pipeline/archives/2017/09/20/alnylam-breaks-through

[2] https://www.fda.gov/Drugs/NewsEvents/ucm615953.htm

to other organs. It will be more challenging to deliver RNAi to other organs, which thus far has been a challenge to do at therapeutically appropriate levels.

Onpattro is encased in a lipid nanoparticle to help carry the drug to the liver and enter the cell. The lipid nanoparticle disrupts the cell membrane to allow Onpattro in to the cell, and thus can trigger an immune response, so patients must prophylactically take a steroid, acetaminophen, and antihistamines. There is thus also the need to find delivery vehicles that are slightly more sophisticated to obviate any immune responses.

HOW DID WE GET HERE?

Pharma entered the RNAi fray in the early 2000s with some big dollar risk-taking in a hot field that would go on to earn a Nobel prize for its scientific discoverers, only to encounter future obstacles. Novartis and Roche paid their way into accessing Alnylam's platform in 2005 and 2007, respectively. Merck paid $1.1bn to acquire Sirna Therapeutics, Alnylam's main competitor at the time. Prior to that transaction, Sirna had a research deal with GlaxoSmithKline as well. Early attempts in ophthalmology and other liver targeted attempts encountered issues with RNA degrading before reaching its target, and thus required extremely high dosing to show any efficacy. Novartis and Roche parted ways with Alnylam in 2010, and Merck eventually sold Sirna IP to Alnylam in early 2014 at a massive discount to its earlier purchase. In the interim, Alnylam soldiered on with some restructuring and a deal with Sanofi dating back to 2012 that helped keep it afloat[3].

LOOKING AHEAD

Alnylam has said the list price for one year of treatment in the US is $450,000 and has at least one value based agreement, with Harvard Pilgrim Health Care. It plans to officially launch Onpattro later this year and will face competition in the US from Ionis and Akcea's also newly approved Tegsedi (inotersen), and possibly also Pfizer's Vyndaqel (tafamidis) before the end of this year.

Alnylam and others are pursuing experimental RNAi treatments in other indications, including acute hepatic porphyrias, cardiovascular disease, hepatitis B, alpha-1 antitrypsin deficiency, primary hyperoxaluria, delayed graft function, and alcohol use disorder[4]. Notably, several of these are also liver-targeted indications with various delivery methods to help with targeting.

- by Christine Livoti

NEW STORY REIGNITES OLD DEBATE ON CONFLICT OF INTEREST

Drug and device development requires extensive expertise, is costly, and time consuming. In particular, the need for deep expertise in many disciplines means there is a market value for those skill sets, and sometimes those exist in the private sector, but many times, in academia. The relationship between academia and industry is both praised and criticized, but unavoidable as increasingly complex diseases are tackled by both parties. As a result, many academics also have some kind of corporate relationship, be it as a trial investigator, a consulting or advisory role, or a speaker's bureau slot, to name a few examples. As these relationships merit payment, critics feel industry payments erode away at academics' ability to offer unbiased opinions and expertise, precipitating the need for some kind of disclosure.

Putting aside the details of the most recent example of a debate over conflict of interest (COI) out of Memorial Sloan Kettering Cancer Center (MSKCC), much of which has already been detailed elsewhere[5], the response suggests disclosure is not only preferred but necessary, though the who, how, and why have yet to be hammered out. Medical journals and some specialty societies may require the data, but do not have uniform criteria for the reporting of industry ties (whether by physicians or sponsors) nor a readily identifiable platform for prospective patients or industry observers to view what relationships physicians may have.

[3] http://cienp.org.br/wp-content/uploads/2018/03/Alnylam-prepares-to-land-first-RNAi-drug-approval.pdf

[4] https://www.wsj.com/articles/fda-approves-first-drug-based-on-gene-silencing-research-1533923359

[5] https://www.nytimes.com/2018/10/12/health/memorial-sloan-kettering-cancer-disclosure.html

The most comprehensive source of information is the Open Payments database maintained by the Centers for Medicare and Medicaid (CMS).[6] Applicable manufacturers and group purchasing organizations are required to annually submit relevant payment information to physicians and teaching hospitals to CMS, and CMS subsequently allows physicians and those hospitals to review the reported payments for accuracy. Payments for research, meals, travel, gifts, and speaking fees are all required to be reported.

While the most comprehensive, there are some notable exemptions to the Open Payment database, which some argue are loopholes asking to be closed. Companies that do not yet have a marketed product approved by the Food and Drug Administration do not have to report payments, meaning many small biotech companies working on their very first product are not reporting to the database. Additionally, continuing medical education (CME) payments are also exempt, though some argue CME is simply another avenue for industry to market their new launches and pipelines.

Referring to the recent MSKCC news, medical ethicist Dr. Arthur Caplan publicly commented "We have yet to figure out what COI means or how to manage it in a health care world where industry ties are everywhere"[7] which is likely the best succinct encapsulation of the status quo. It is unknown what payment threshold might influence physician decision making (whether perceived or actual), but there is also some intangible value to physicians who serve as investigators on cutting edge clinical trials and serve on advisory boards alongside the top minds in their fields, who in turn can provide better care for their patients. It would be wrong to suggest that all interactions between industry and physicians are either unethical or inappropriate, but we can, and should, do better at reporting them.

- by Christine Livoti

[6] https://openpaymentsdata.cms.gov/

[7] https://twitter.com/ArthurCaplan/status/1038849711174762499

PEER-REVIEWED ABSTRACTS

As part of Deerfield's mission of advancing healthcare, the Deerfield Institute is committed to publishing its proprietary research in peer-reviewed, open access scientific journals. Below is a selection of some of our recently published work. More information on the Deerfield Institute, and copies of certain past publications are available on the web at Deerfield.com/Institute.

SCIENTIFIC REPORTS

PERSISTING DISPARITIES BETWEEN SEXES IN OUTCOMES OF RUPTURED ABDOMINAL AORTIC ANEURYSM HOSPITALIZATIONS

MARK STUNTZ, CELINE AUDIBERT, ZHENG SU

ABSTRACT

We sought to describe and analyze discrepancies between sexes in the outcomes of patients hospitalized for ruptured abdominal aortic aneurysms (rAAA) by conducting a retrospective analysis of the Nationwide Inpatient Sample. The review included all adult patients (≥18 years old) hospitalized with a primary diagnosis of rAAA between January 2002 and December 2014. In-hospital mortality differences between females and males were analyzed overall and separately among those receiving endovascular AAA repair (EVAR) or open AAA repair (OAR). In-hospital mortality for females declined from 61.0% in 2002 to 49.0% in 2014 (P for trend <0.001), while mortality for males declined from 48.6% in 2002 to 32.2% in 2014 (P for trend <0.001). Among those receiving EVAR, females were significantly more likely to die in the hospital than males (adjusted odds ratio [OR], 1.44; 95% CI, 1.12–1.84). In addition, the odds of mortality among those receiving OAR were higher for females than males (adjusted OR, 1.14; 95% CI: 1.00–1.31). These data provide evidence that despite overall decreasing trends in mortality for both sexes, females remain at higher risk of death compared with males regardless of surgical repair procedure.

IP CORNER

Intellectual Property (IP) is a vital asset to any emerging company in the healthcare space. Here, we highlight noteworthy trends and events in the IP realm with implications for both young and established healthcare companies alike.

2018 PATENTS FOR HUMANITY AWARDS

Patents for Humanity is a United States Patent and Trademark Office (USPTO) awards program that was started in 2012 to recognize and encourage the application of innovative technologies to solve problems in underserved or impoverished communities. These struggling communities are unable to attract as much commercial interest for a variety of reasons, including the lack of capital, lack of infrastructure, low education levels, or insufficient legal protections. The awards seek to offset the diminished commercial incentives as well as recognize innovators who prevailed against these challenges to bring life-changing technologies to those in need. On August 9, 2018, the USPTO announced this year's winners of the Patents for Humanity awards.

From nine winners selected this year, four were in the field of healthcare:

1. Medtronic won the award for its creation of a portable low-water use kidney dialysis machine. The machine uses only about 20 liters of water per treatment, roughly a quarter of the amount required by current systems. It weighs 50 pounds and is the size of a small suitcase. Approximately 700 million people in the world today are in need of dialysis. This new dialysis machine can bring these life-saving treatments to many patients in the developing countries that lack the infrastructure to provide stationary machines that demand huge quantities of water.
2. The U.S. National Institutes of Health won the award for creating a low-cost rotavirus vaccine that remains stable for two years without refrigeration. Rotaviruses cause severe diarrhea that results in more than 200,000 child deaths worldwide each year. The award-winning vaccine addresses six of the most common rotaviruses. The government of India has already ordered 3.8 million doses for its Universal Vaccination Program.
3. Little Sparrow Technologies won the award for developing a low-cost device for treating jaundice in infants. Jaundice causes approximately 100,000 infant deaths annually in developing countries. These deaths are fully preventable, but the current devices were too expensive for most developing countries. Little Sparrow's machine runs on battery power, collapses for easy transportation, and is built from off-the-shelf parts. The World Health Organization included this device in its Compendium of Medical Devices for Global Health.
4. Kinnos Inc. won the award for creating a color-changing chemical additive for chlorine which helps to indicate proper surface disinfection with chlorine in Ebola treatment centers. The additive turns the surface blue to indicate that it has been properly disinfected. The color fades with time so healthcare workers can easily see if a surface needs additional treatment. The additive has already been used in Liberia, Guinea, Haiti, Uganda, and Democratic Republic of Congo. The Hazmat team of New York Fire Department has also been using this additive.

The USPTO also named six honorable mentions. We would like to recognize that one of our partners,[8] Vanderbilt University, was awarded an honorable mention for developing and distributing antibodies for the Zika virus to other researchers.[9] The antibodies enable further work to develop vaccines and treatments.

[8] http://deerfield.com/PressRelease.aspx?PressReleaseID=142
[9] https://cttc.co/blog/20180809/uspto-awards-crowe-lab-and-vanderbilt-honorable-mention-2018s-patents-humanity-winners

Congratulations to all the winners! As stated by Edward Elliott, the program manager of Patents for Humanity, "Patents for Humanity seeks to recognize innovators of all types by celebrating their varied contributions to our common goal: bringing prosperity to every corner of the globe."[10] These recipients show how even a small group of dedicated people can impact lives around the world.

- by Mark Shtilerman, Senior Counsel

[10] http://www.wipo.int/wipo_magazine/en/2017/02/article_0003.html

CAUGHT OUR EYE

The Centers for Medicare and Medicaid (CMS) quietly killed plans earlier this year for a pay-for-performance model for the CAR-T drug Kymriah. If implemented, it would have been the first of its kind arrangement for the US government. When the Novartis drug won approval last year, a company press release mentioned collaboration with CMS was underway to create a money back guarantee from Novartis to cover the drug costs for patients who failed to respond one month after the one-time treatment. After nearly a year without further details, it was revealed the plans were killed, in the course of the Congressional inquiry into the relationship between Novartis and Michael Cohen, President Trump's former lawyer. Politico

The Food and Drug Administration released a slew of guidance documents meant to provide clear recommendations to drug makers developing gene therapy products. Three guidances focus on specific disease categories – hemophilia, retinal disorders, and rare diseases. Three additional guidances focus on Chemistry, Manufacturing, and Control (typically dubbed CMC) Information, testing for Replication Competent Retrovirus, and long term follow up. The agency is still receiving feedback via the open comment period. FDA

The state of Louisiana is currently evaluating a subscription payment model for its HCV-infected Medicaid population. The proposed plan would pool together resources dedicated to covering Medicaid patients and the uninsured to then pay Gilead Sciences a fixed dollar amount for several years in return for its HCV drug Sovaldi. During the first few years, the state would ultimately receive more drug than it pays for, but as the state moves through and ultimately cures its HCV patients, it would have fewer patients to treat while paying Gilead the same fixed amount of money agreed upon in the scheme. Outside of this payment scheme, Sovaldi costs over $80,000 for a 12-week course of payment, making it prohibitively expensive for cash-strapped Medicaid plans. A decision on the plan is expected by the end of this year. NPR

Google recently resumed allowing addiction treatment centers to buy search engine advertisements through its AdWords program after the search engine itself curtailed the program last year. Now, only organizations vetted through a third party, LegitScript, will be certified to advertise on the platform in an attempt to funnel prospective patients away from disreputable treatment centers. LegitScript has approved more than 335 unique facilities in the first phase of its certification program. Not long after the Google/LegitScript relationship was announced, Facebook similarly announced it would be using LegitScript to certify advertisements from addiction centers on the social networking platform. LegitScript

A recent white paper from CVS Health indicated the integrated drug store chain and pharmaceutical benefit manager (PBM) would be using cost-benefit determinations from the Institute for Clinical and Economic Review (ICER) as grounds to deny drug coverage. Drugs launched at a price greater than $100,000 per quality-adjusted life year (QALY) can be excluded from coverage, though breakthrough-designated drugs will fall outside the scope of this effort. QALY is a commonly used measure in health economics. CVS Health

Amid increasing finger pointing from healthcare stakeholders over rising healthcare costs, an internal look by Harvard Pilgrim, a commercial insurer with about one million covered lives, found that prescription drugs accounted for about 25% of all costs. From 2011 to 2016, the plan's spending on pharmaceuticals increased from 20 to 25% of total spending, and, since 2014, medication spending has been greater than inpatient care spending. Of all drug spending in 2016, about 75% was under the pharmacy benefit (patient administered) while the remainder was under medical benefit (physician administered). The plan has been able to avoid increases in copayments for plan members, which it attributes to contracting and formulary design. *Health Affairs Blog*

The FDA announced additional payer participation in its Private Payer Program, designed to help device manufacturers receive market access advice feedback while still in development. The program now includes eight organizations – CareFirst BlueCross BlueShield, United Health Group, BlueCross BlueShield Association, Duke Evidence Synthesis Group, ECRI Institute, Humana, Kaiser Permanente, and the National Institute for Health and Care Excellence (NICE). FDA

DEERFIELD FOUNDATION

The Foundation has formed 39 partnerships and invested or committed approximately $36 million for the advancement of children's health in its 10 years, ranging from health clinics in Nepal to a mobile medical home for children in the South Bronx. In this newsletter we would like to highlight just one of the organizations that we feel is helping us fulfill our mission of advancing healthcare. We are proud to be critical supporters of Lwala.

LWALA

Mission:	To build the capacity of rural communities to advance their own comprehensive well being.
Partner Since:	2017
Description:	Lwala Community Alliance (Lwala) catalyzes the capabilities of communities to tackle the multidimensional drivers of poor health. It was founded by a group of community members in rural Kenya facing the dual crisis of maternal and child mortality, who organized to build their region's first health clinic and then engaged the research prowess of Vanderbilt University to rigorously measure its interventions. Today, Lwala is much more than a hospital; it operates a community-led health model making dramatic improvements in maternal and child health, including a 97% skilled delivery rate, 300% increase in contraceptive uptake, 64% reduction in child mortality, 96% immunization rate, and virtual elimination of mother-to-child transmission of HIV.
Total Funding:	$80,000
The Deerfield Perspective:	Migori County, where Lwala operates, has some of the highest rates of maternal and child deaths in Kenya. Before 2001 when the organization began, 105/1,000 children died before they reached their 5th birthday in Lwala's catchment area. Today, that number has been slashed to 29.5/1000 children, a result of Lwala's innovative approach to engaging communities to develop solutions to their own health challenges. Further , Kenya's Ministry of Health has invited Lwala to scale its community-led approach throughout Migori County, ultimately influencing how approximately 1 million people access health care. Deerfield has been impressed with the impact and effectiveness of Lwala's model, and encouraged by its early successes in replicating their approach.
Lwala Perspective:	Lwala rejects the notion that grassroots initiative are not scalable. Indeed, community-led interventions can transform systems of inequity by leveraging the latent capacity of vulnerable communities. Because of this, we believe that bottom-up solutions matched with research-backed technology are uniquely positioned for systems change. We are leading the charge on implementing life-saving technologies and interventions in Migori County, setting the stage to ultimately influence national maternal and child health curriculum in Kenya, and the nation's wider health system
Most Recent Projects Funded:	Deerfield supports Lwala's approach to strengthening health systems to reduce maternal and child mortality. Since the grant began in 2017, Lwala has: ▪ More than doubled its catchment area to ~60,000 people ▪ Provided high-quality care to 5,044 mothers and 7,598 children through our community-based health program ▪ Maintained a skilled delivery rate of 98% and immunization rate of 95% ▪ Treated 1,362 children were malaria (1,025 in the facility and 337 in the community) ▪ Provided 11,889 couple years of protection, a measure of contraceptives provided (intrauterine devices, implants, injections, and birth control pills) weighted by the number of years of prevented pregnancy ▪ 1,623 individuals received HIV care through our community-based HIV and WASH integrated program and 50 infants graduated from our elimination of mother-to-child transmission of HIV (eMTCT) program after testing negative at 18-months ▪ So far in 2018, 65 mother-child pairs have been enrolled into the elimination of mother-to-child transmission program for graduation this November ▪ The HIV patient default rate has remained below our target of 10% for the entirety of the grant period

NEWS YOU MAY HAVE MISSED

We've been busy at Deerfield the last few months! Here is a sampling of some of what we've been up to:

Bridge Medicines Enters Agreement with Memorial Sloan Kettering to Develop Kidney-Specific Delivery Platform for the Treatment of Acute Kidney Injury

July 23, 2018
Read More

University of California San Diego and Deerfield Management Create Poseidon Innovation to Advance Disease-Curing Therapeutics

September 05, 2018
Read More

Deerfield and Stan Rowe Create a Next Generation Therapeutic Device Incubator, NXT Biomedical

September 20, 2018
Read More

NEWS FROM OUR FOUNDATION PARTNERS

Our Deerfield Foundation Partners are hard at work advancing children's health. Below we will highlight brief updates:

The Water Trust Presents Three Papers at the WEDC International Conference

July 26, 2018
Representatives of The Water Trust presented three papers at the Water, Engineering and Development Centre (WEDC) of Loughsborough University's 41st International Conference detailing findings of their village and school programs in Western Uganda to improve sanitation and hygiene.
Read More

SHE Featured in New Smithsonian Exhibit

On September 13th, SHE's go! pad was featured in the Smithsonian's latest exhibit, Design with the 90%. The exhibit highlights connections between a variety of issues related to the work of the Gates Foundation, its partners, and the Seattle community. Partner museums and organizations include the American Museum of Natural History and the Cooper Hewitt, Smithsonian Design Museum to showcase relevant topics, build awareness of global and local issues, and inspire action. The exhibit will be on view through May 11, 2019.
Read More

Lwala publishes results of child mortality study

A recent paper from Lwala showed the intervention of its community health workers in Migori County, Kenya, reduced the under five mortality rate roughly in half. Prior to Lwala intervention in that area, the under five mortality rate was 104.8 per 1,000, and the rate after Lwala intervention is 53 per 1,000.
Read More

MEET THE ASSOCIATES

Beginning in 2015, Deerfield started the Deerfield Fellows program, designed to attract students with interest in pursuing healthcare or finance fields from local NYC-area colleges and universities from diverse backgrounds for an immersive summer internship program. Successful summer interns are invited to stay through a yearlong Deerfield Fellowship program, with the most successful of those graduating to become Associates at Deerfield. We are extremely proud of the work our Associates do, and here will highlight an Associate in each issue.

MEET ANIKA ALI

WHAT INITIALLY DREW YOU TO THE FELLOWS PROGRAM?
I had done a couple of finance internships before but never one that specialized in a specific sector. I liked the idea of Wall Street but also giving back to the world as healthcare is a universal need. Additionally, I was amazed by all the philanthropic work Deerfield did which was one of the factors that drew me in.

WHAT IN YOUR EXPERIENCE HAS MATCHED YOUR EXPECTATIONS ABOUT BEING A DEERFIELD FELLOW AND NOW ASSOCIATE?
As a fellow, I had expectations that I would learn a great deal about the healthcare system. After the summer and year-long fellowship, I did gain a fair amount knowledge about the US healthcare system and it opened my eyes to organizations that I never thought existed before, like pharmacy benefit managers! It was fascinating to learn the process of how a drug is first discovered in the lab to how it ends up sitting on my nightstand.

As an associate, I want to gain more insight into how the moving parts in Deerfield work together to ultimately make an investment decision.

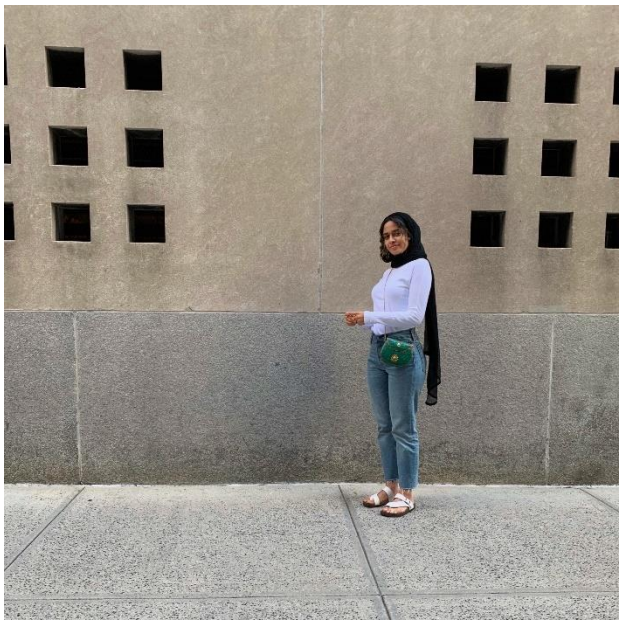

Photo courtesy Anika Ali

DESCRIBE A TIME OR TIMES YOU FOUND TO BE UNEXPECTED.
I was taken aback by the culture at Deerfield, and how it does not feel like a typical corporate firm. People here are willing to put time aside from their busy schedule to genuinely help.

WHAT ADVICE WOULD YOU GIVE TO FUTURE FELLOWS?
Don't be afraid to ask for help! If you don't understand something, make sure to ask.

WHEN NOT AT DEERFIELD, I CAN BE FOUND:
Wandering in nature.

ONE FUN FACT ABOUT YOU!
I can read Arabic fluently but not understand a word of what I'm saying.

IMPORTANT NOTES AND DISCLAIMER

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