

## MESSAGE from the President

We are closing the year 2015 with this 8th edition recognizing the value of our work in each of the respective organizations we are involved with. During this term we celebrated the 26th PIA Annual Meeting, adding tools of leadership and teamwork through each lecture held at the event. Deliberately, the committee has chosen dynamic exercises and themes to inspire us to continue carrying out our tasks with integrity and excellence. Also, PIA elected new Directors and Officers to be part of the Board during 2016 and 2017. We look forward to a seamless integration of these new board members. In this edition we are pleased to present important information that reflects the contribution of the industry and new products available to improve the health and wellness of people. Thank you for your collaboration. May this Holiday Season be full of joy and quality time with your loved ones.



Robert Maroney

## New PIA Board Directors and Officers

On Friday, November 6th, 2015, PIA had the 2015 Annual Assembly. As part of the Assembly, they elected new Directors and Officers to the Board for 2016/2017.

- Directors:**
- **Felipe Palacios** – GM AbbVie, P.R. Commercial Operations
  - **Andrew Willy** – GM Amgen P.R. Commercial Operations
  - **Mario Sturion** – GM J&J P.R. Commercial Operations
  - **José Viera** – GM Allergan P.R. Commercial Operations
  - **Anibal Carlo** – GM BMS Manati, P.R. Manufacturing Operations
  - **John O'Hara** – GM J&J Janssen, Gurabo P.R. Manufacturing Operations
  - **Ileana Quiñones** – GM AstraZeneca, P.R. Manufacturing Operations
- Officers:**
- **Robert Maroney** – VP & GM Amgen P.R. Manufacturing Operations, President
  - **Lourdes Colón** – VP & GM Lilly, PR Manufacturing Operations, Vice-President
  - **Elsa Saavedra** – GM AstraZeneca, PR Commercial Operations, Secretary
  - **David Thompson** – GM AbbVie Barceloneta Manufacturing Operations, Treasurer

# PIA 26<sup>th</sup> Annual Meeting



## THE AMGEN FOUNDATION ANNOUNCES NEW \$4 MILLION COMMITMENT TO BRING HANDS-ON LABS TO SECONDARY SCHOOL STUDENTS

The Amgen Biotech Experience will reach more than 150,000 Students over next Two Years

The Amgen Foundation announced it will invest more than \$4 million to support and strengthen the **Amgen Biotech Experience (ABE)** program across the United States, Puerto Rico, United Kingdom and Ireland.

Celebrating its **25th anniversary** this year, the ABE labs were designed by Amgen scientists and educators to inspire the next generation of innovators and give every biology student the opportunity to experience real science at their fingertips. ABE does this by providing hundreds of secondary school teachers with advanced training, curriculum and research-grade equipment that empowers them to run biotechnology labs in their classrooms, labs that incorporate the core technologies used by the biotech industry in the discovery of human therapeutics. Through such teachers, 72,000 students across Amgen regions participated in the ABE labs this past year.



For its part, Dr. Héctor Ayala del Río, Program Director of Amgen Biotech Experience and Professor in the Department of Biology at University of Puerto Rico, Humacao campus, indicated: "For the past eight years Amgen Biotech Experience Program has provided educational tools to the schoolteachers to make the science class interactive and exciting. The students have had the opportunity to make experiments while learning about Biotechnology. This results in prepared students to pursue careers in science." He also added that the initiative has impacted more than 70 teachers and 8,000 student from the public and private educational system in Puerto Rico during the academic period 2014-2015.

## GSK profiles innovative R&D portfolio to investor

At a presentation to investors in New York, GSK described a deep portfolio of innovation, focussed across six core areas of scientific research and development: HIV & Infectious diseases, Oncology, Immuno-Inflammation, Vaccines, Respiratory and Rare Diseases. Around 40 new potential medicines and vaccines were profiled, supporting the Group's outlook for growth in the period 2016-2020 and the significant opportunity the Group has to create value beyond 2020.

The portfolio represents some of the latest scientific achievements from GSK's R&D organisation and its more than 1,500 company and academic collaborations. The company believes approximately 80% of the medicines and vaccines presented have the potential to be "first-in-class" with novel mechanisms of action. As a result, many of these potential medicines and vaccines may offer benefits beyond current standards of care and, in some cases, could radically transform how patients are treated.

**Sir Andrew Witty, CEO GSK said: "Earlier this year we set out our expectations for the Group to generate sustained sales and earnings performance over the next 5 years. With the recent transaction, we have significantly strengthened our Vaccines and Consumer Healthcare businesses."**

"The level of innovation in this portfolio is substantial. We believe this is critical in today's operating environment as payors look to balance pressures of pricing and demand. It also provides us with confidence that this portfolio can generate significant value for shareholders and deliver widespread benefits to patients and consumers."

## Pfizer Recognized by the PR Red Cross with the 2015 Good Neighbor Award for Home Fire Prevention Support

Home fires are the main cause of death by fire in Puerto Rico, and Pfizer joined the Red Cross PR Chapter in a campaign to help prevent them. Thanks to a grant from the company, home fire prevention events have been conducted in at-risk communities in Barceloneta, Vega Baja, and shortly, in Guayama. The three municipalities where PGS maintains operations.

During the events, brigades of volunteers along with Pfizer colleagues go door by door installing smoke detectors in homes and educating residents on how to prevent home fires. Each event impacts close to 140 homes. During the Annual Assembly of the American Red Cross, Puerto Rico Chapter, Pfizer received the "2015 Good Neighbor Award" granted each year to an organization or individual who has made a significant humanitarian contribution to the community through the Red Cross, PR Chapter. This is the highest award granted by the Chapter.



## GSK Nucala® (mepolizumab) receives approval from US FDA

First anti-IL5 treatment for adults and adolescents with severe asthma with an eosinophilic phenotype

GlaxoSmithKline plc (LSE/NYSE: GSK) received on November an approval from the US Food and Drug Administration (FDA) for its Biologics License Application (BLA) for Nucala® (mepolizumab) as an add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Nucala is the first and only approved biologic therapy that targets interleukin-5 (IL-5), which plays an important role in regulating the function of eosinophils, an inflammatory cell known to be important in asthma. It is administered as a 100mg fixed dose subcutaneous injection every four weeks. Patients will receive Nucala in addition to their normal medications for severe asthma, which include high-dose inhaled corticosteroids plus at least one additional asthma control medicine, and may include oral corticosteroids.

This is the first marketing authorization granted for mepolizumab anywhere in the world.

Eric Dube, Senior Vice President & Head, GSK Global Respiratory Franchise, said: "Following today's approval, GSK can now offer, as part of our overall respiratory portfolio, a first-in-class biologic treatment for severe asthma patients whose condition is driven by eosinophilic inflammation. Our research has allowed us to better understand the specific role eosinophils play in severe asthma. We are proud of our contribution to this emerging area of science that has led to the approval of the first anti-IL5 treatment. We aim to offer this medicine to patients as soon as possible."



## Pfizer's Global Technology Services Set to Transform Pharmaceutical Manufacturing

For a generation of patients, medicines have turned once-deadly diseases like diabetes and heart disease into preventable conditions that can be managed with proper medical care. However, the core processes used to manufacture most medicines prescribed today are high technology versions of processes established more than 50 years ago. The Advanced Manufacturing Technology (AMT) team from Pfizer's Global Technology Services (GTS) is shifting pharmaceutical manufacturing.

The AMT team was in Puerto Rico to deliver a seminar on "Trends in Advanced Pharmaceutical Manufacturing." The University of Puerto Rico's Chemical Engineering Department was the venue for the event, which brought together representatives from pharmaceutical companies, academia and government agencies.

**"The XL platform we have in Puerto Rico is still one of the most sophisticated Extended Release technologies available. Furthermore, the island is a rapid launch site for products for the US market, as was recently the case with Ibrance. As a result, it was natural we decided to organize this seminar with a local university to promote technology development,"**

said Kevin Nepveux, Vice President Global Technology Services in his opening remarks.

Technology and Business Solutions in his keynote speech, addressing the need for disruptive innovation and advances as a first step in transforming pharmaceutical manufacturing.



To support the industry in this process, Pfizer has launched "Intellicentric™" a branded service to promote open innovation and noncompetitive collaboration. "Manufacturing excellence is not possible in isolation," says Mojgan Moshgbar, Director Advanced Manufacturing Technology. "Intellicentric is a new venture in Pfizer where we are willing to share platform technologies with other companies, academia and contractors to promote the uptake of technology, accelerate regulatory awareness and reduce external barriers to its use." This technology provides greater agility, a competitive advantage these days because products are more expensive and there are many more SKU's. According to Moshgbar, "the way to achieve agility in this scenario is through collaboration between companies and contractors so they can deliver their products faster." Talent development is also a key enabler and academia needs to be involved to develop the talent to sustain and energize the uptake of technology.

# Who We Are? PACIV

Puerto Rico has been ranked third on economic, financial and business strength by FDI Intelligence's 2015/2016 Top 10 Caribbean & Central American Countries of the Future. Puerto Rico's economic potential, connectivity and business friendliness locked in its place as third in the region. The island's economic development incentives to attract investment in manufacturing, tourism and renewable energy helped as well.

The Biopharmaceutical industry has been the leading industrial sector in Puerto Rico's economic development since the mid 70's and has made unparalleled contributions to the economy. Its contribution to Gross Domestic Product (GDP), to our human capital formation and employment, to our academic areas, to our infrastructure and to our secondary economic activity, it's unprecedented. However, in recent months there has been increased criticism of the Foreign Direct Investment (FDI). There are two types of foreign direct investment that we have experienced in the island (Consumer & Industrial). Both play an important role in the sustainable socio-economic development of any society; however, it is important to distinguish that there are fundamental differences in both.

Industrial foreign direct investment, which in Puerto Rico is mainly biopharmaceutical and medical devices, has injected billions of dollars to create its facilities, implement world-class technologies and in the process build wealth for the country and its residents. Moreover, to stay in world-class operation, they require significant consumption of utilities, high-level paying jobs, developed

infrastructure and an on-going investment in its facilities. These biopharmaceutical companies came here about 50 years ago and led an industrialization in Puerto Rico of leading innovation, high technology and science, that converted Puerto Rico from one of the poorest economies in Latin America, to the country in that region with the highest income per capita. It all happened over a 30 year timeframe. Basically, the wealth that takes most societies 100 years to generate, Puerto Rico created it in about 30 years.

In Puerto Rico, our income per capita exceeds \$18,000 while in Latin America averages less than \$3,000. In addition, while the average salary in Puerto Rico does not exceed \$12,000, the salaries in the biopharmaceutical industry average \$68,000. In Puerto Rico, of over 40,000 companies and over a million individuals filing tax returns, fourteen (14) biopharmaceutical companies are responsible for over 33% of the total tax dollar returns; next closest industry is Tourism with 7% (counting the hotel room stays of business travel). This does not include the taxes paid by their employees, by their suppliers and their employees, and other secondary and tertiary economic activity that this industry creates. Moreover, the CapEx of these facilities on a yearly basis, exceed \$500 million per year without taking into account expansions and/or product transfers.

It is time for Puerto Rico, its citizens and residents, and those directly or indirectly employed by this industry, to begin recognizing and thanking this industry for all they have done for over 50 years in Puerto Rico.