New oncology partnerships encompass entire value chain

A new partnership with Hanmi Pharmaceutical Co. Ltd. seeks to strengthen Boehringer Ingelheim’s successfully marketed portfolio in non-small cell lung cancer (NSCLC) through an exclusive license and collaboration agreement for the development and commercialization of a novel, third-generation epidermal growth factor receptor (EGFR) targeted therapy.

HM61713 (BI 1482694) is an orally active, irreversible, EGFR mutation-selective, tyrosine kinase inhibitor. The compound is currently in Phase II clinical development after having demonstrated strong efficacy signals and a favorable safety profile in interim results of the Phase I/II trial presented at the ASCO 2015 Annual Meeting1. Boehringer Ingelheim has recently initiated a pivotal Phase II study evaluating the efficacy and safety of HM61713 in patients with T790M mutation-positive NSCLC, whose tumors have stopped responding to currently available EGFR-directed therapies.

With the inclusion of HM61713, Boehringer Ingelheim now has more than ten new molecular entities in clinical development in a wide variety of oncology indications.

“Boehringer Ingelheim has significant expertise in the field of lung cancer, specifically in EGFR-mutated disease. The Company’s strong pipeline demonstrates its long-term commitment to successful development of cancer treatments and we are confident we have found the right partner to make the potential of HM61713 a reality.”

Dr Jeewoong Son, Chief Medical Officer, Hanmi Pharmaceutical.

The collaboration will focus on identifying and developing therapeutic concepts in novel target areas as well as the identification of biomarkers that can accurately identify patients who would respond to potential new therapies.

Boehringer Ingelheim is also building a strong pipeline in hematological cancers with several compounds currently being investigated in ongoing clinical trials in a number of indications. This portfolio has recently been strengthened with a new collaboration with Philogen that seeks to investigate novel immunotherapy concepts for relapsed patients with acute myeloid leukemia (AML). There is a particularly high medical need in AML as it has one of the lowest survival rates of all leukemias.

“With its impressive success in bringing innovative new therapies to market and its broad experience in oncology research and development, Boehringer Ingelheim is the right partner to accelerate the transition of our novel targeted therapies into clinical development.” Dr. Duccio Neri, CEO, Philogen.

Boosting our Connectivity with Boston Life-Sciences Hub

Boehringer Ingelheim recognizes the important contributions to innovation of the many biotechnology companies and academic institutions in the Boston area and as a result, is increasing its accessibility in the region.

Most recently, the Company actively participated in the annual BioPharm America partnering conference in September by contributing to panel discussions and presentations, and by hosting a ‘Lounge’ where delegates could meet the partnering team. This was followed in October by a dedicated partnering day, held in conjunction with the Massachusetts Biotechnology Council (MassBio). The event, said by MassBio to be the largest of its kind, was attended by members of Boehringer Ingelheim’s partnering and research leadership team and more than 200 industry and academic innovators and entrepreneurs seeking to learn more about partnering with the Company. Delegates had the chance to participate in therapy area-specific discussions, one-on-one meetings and hear presentations on the Company’s research strategy, key opportunities for partnering and the Venture Fund.

Demonstrating its commitment to supporting innovation, through championing early-stage entrepreneurs and helping them bring their ideas to market, Boehringer Ingelheim, together with the Boehringer Ingelheim Venture Fund, presented its inaugural Innovation Prize of $50,000 at the event. The award provided a platform to show-case ideas and projects from entrepreneurs and start-up organizations, and close to 60 entries were received. The top 15 applicants were invited to present their ideas in a poster session, from which a final short-list of five was selected to present their ideas to a panel of judges who chose Kleo Pharmaceuticals as the winner. Kleo is focused on developing novel small molecule-based immunotherapies capable of performing the same functions as biologics, but with improved properties.

“We are delighted with the success of our Partnering day in Boston which has provided a forum to meet biotechnology companies and academic institutes in the region to discuss how we can work together for better health. Our Innovation Prize has also highlighted some exciting new thinking and we look forward to establishing new collaborations with the potential partners we have met today to realize their visions and ideas for the benefit of patients around the world.”

Dr. Paola Casarosa, Corporate Vice President, Business Development and Licensing, Prescription Medicines.

Embracing the Revolutionary Power of Open Innovation

At Boehringer Ingelheim we are currently exploring and embedding a wide range of open innovation opportunities in our own early research endeavours in three different ways:

Bilateral collaborations remain a cornerstone of our partnering activities. Two very recent examples of this are the collaborations with The University of Texas MD Anderson Cancer Center in pancreatic cancer and a series of four research collaborations, in inflammatory bowel disease, with the Icahn School of Medicine at Mount Sinai, New York; Massachusetts General Hospital, Boston, Massachusetts; The Scripps Research Institute, La Jolla, California and Weill Cornell Medicine, New York.

Public-private partnerships play an important role because of their ability to bring together the best academic and industry scientists unencumbered by restrictions to operate. Boehringer Ingelheim has recently joined the G-protein coupled receptor (GPCR) Consortium, and we continue to be committed to the Structural Genomics Consortium (SGC) and the Innovative Medicines Initiative (IMI). The power of these partnerships has been demonstrated, for example, by the use of the chemical tools in epigenetic research by the SGC. By creating a community-driven wiki resource (www. chemicalprobes.org), the optimal use of such chemical tools, and early target discovery is enabled.

Crowdsourcing initiatives with specialized providers, such as InnoCentive and the BioMed X Innovation Center, are being used to find scientists with bright ideas to address important medical challenges. As part of the collaboration with the BioMed X Innovation Center, a research team has started a discovery project on epigenetic regulators in COPD, and a second project has been launched to explore novel target ideas for the treatment of psychiatric diseases. Such approaches help us explore emerging science beyond our current network and access breakthrough technologies and expertise.

We recognize that innovation is an iterative and team-driven process, by which creative ideas are converted into practice in the form of new medicines. This must take place in an open environment of collaboration and partnership and we continue to seek new partners to join us in working together for better health.

Sources of Open Innovation
In Focus... Research Beyond Borders

Our Company vision is “Value through Innovation”. This principle is the cornerstone of Boehringer Ingelheim’s research and development strategy and drives us in our search for new therapeutic options to deliver improved efficacy and/or quality of life benefits to the patients we serve. In a rapidly changing scientific environment we continually seek to be at the forefront of the next wave of scientific and medical innovation to ensure that no unmet medical need or promising scientific advance is left behind in our pursuit of new healthcare solutions.

Research Beyond Borders aims to achieve this goal by enhancing our capacity for innovation and encouraging scientific creativity. We recognize the need to broaden the scope of our research activities and explore emerging science and technology, both within and beyond our therapeutic areas of focus, to enable a fast and efficient entry into new indications, novel target spaces and innovative therapeutic modalities:

- **Breakthrough discoveries in new indications** with high unmet medical need such as rare diseases and hearing and ophthalmological disorders
- **Innovative therapeutic modalities** such as gene therapy, cell-based therapy and gene-editing
- **Novel target spaces** such as the microbiome and regenerative medicine.

To accomplish this, Research Beyond Borders integrates internal and external insights and opportunities, and explores new models for collaboration, to bring together the talents and capabilities of our scientists most effectively with the strengths of innovation partners across the world, who seek to join us in working together for better health.

“Our Research Beyond Borders collaborative teams are working in innovation hotspots in North America, Europe and Asia pursuing ground-breaking science. To be successful we focus on building highly collaborative relationships by establishing a committed and active presence in strategic areas of interest within the scientific community. We are excited to broaden the scope of our research activities and look forward to growing our potential to accelerate the discovery and development of solutions to address the health needs of patients around the world.”

Dr. Henri Doods, Vice President Global Department Research Beyond Borders, Boehringer Ingelheim.

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**Research Beyond Borders: High Priority Scientific Areas**

**Hearing Loss**
Exploration of mechanisms/targets involved in hearing disorders to develop solutions for this high unmet medical need

**Gene Therapy**
Development of a focused portfolio of therapeutic concepts and technology enhancements

**Microbiome**
Identification of novel bacteria and bacterial products; and establishing their causal role in human health and disease

**Regenerative Medicine**
New targets, or methods for identifying targets, implicated in the mobilization and/or differentiation of endogenous stem cells/progenitor cells
New Partnerships Augment Immunology and CardioMetabolic Diseases’ Pipelines

Comprehensive research program in Inflammatory Bowel Disease announced with leading scientific institutions

Boehringer Ingelheim has announced a series of four research collaborations with major scientific partners to enrich research and development of novel therapeutic approaches for the treatment of Crohn’s disease and ulcerative colitis.

The collaborations with the Icahn School of Medicine at Mount Sinai, New York; Massachusetts General Hospital, Boston, Massachusetts; The Scripps Research Institute, La Jolla, California and Weill Cornell Medicine, New York; aim to identify and validate potential new therapeutic targets as well as identify biomarkers that offer the potential to address the significant unmet medical needs of patients with inflammatory bowel diseases (IBD).

“Academia-industry collaborations are an extraordinarily effective way to advance research and we recognize the importance of joining forces with leading experts to develop innovative therapies. With these collaborations we aim to transform the treatment of immune diseases to improve the lives of patients and those that care for them” said Dr. Clive Wood, Senior Corporate Vice President Discovery Research, Boehringer Ingelheim.

Second research collaboration with Circuit Therapeutics aims to discover new medicines for obesity

Boehringer Ingelheim and Circuit Therapeutics recently announced a second collaboration utilizing Circuit’s proprietary optogenetics technology platform. This new collaboration will focus on investigating metabolic disorders with the aim of developing novel medicines to improve the treatment of obesity and associated diseases. The companies’ first partnership, which is still ongoing, focuses on the discovery of new treatments for neuropsychiatric disorders.

“We are excited to extend our partnership with Boehringer Ingelheim and use Circuit’s technological capabilities to advance drug discovery in another therapeutic area. The success of our first collaboration is founded in Boehringer Ingelheim’s unique partnering approach and its outstanding internal drug discovery capabilities. Together we aspire to establish a foundation for the development of transformational drugs to impact patients’ lives,” said Fred Moll, Chairman of Circuit Therapeutics.