

Boehringer Ingelheim Expands KRAS Cancer Program with Lupin's Clinical Stage MEK Inhibitor Compound

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Boehringer Ingelheim strengthens its pipeline portfolio for patients with gastrointestinal and lung cancers with this new licensing, development and commercialization agreement



Boehringer Ingelheim and Lupin Limited (Lupin) has announced a licensing, development and commercialization agreement for Lupin's MEK inhibitor compound (LNP3794) as a potential targeted therapy for patients with difficult-to-treat cancers. The partnership aims to develop Lupin's lead MEK inhibitor compound in combination with one of Boehringer Ingelheim's innovative KRAS inhibitors for patients with gastrointestinal and lung cancers harboring a broad range of oncogenic KRAS mutations.

"The licensing of Lupin's novel MEK inhibitor enables us to pair with our innovative KRAS inhibitors to develop new combination treatment concepts providing more effective and durable responses for patients with cancers driven by activated KRAS who currently have limited treatment options available," said Norbert Kraut, Ph.D., Head of Global Cancer Research at Boehringer Ingelheim. "We believe this collaboration will significantly strengthen our KRAS program. We have developed comprehensive approaches to successfully tackle the oncogenic KRAS-RAF-MEK-ERK pathway from the ground up and this partnership is another key building block in our long-term strategy to bring novel treatments to patients in our quest to defeat intractable cancer types."

Commenting on the partnership, Nilesh Gupta, Managing Director, Lupin Limited said, "With the success of our second new

drug discovery program in oncology, we have made a significant mark in bringing novel treatments to patients. Lupin's MEK Inhibitor program successfully cleared early clinical stages, demonstrating our capabilities in delivering world class innovation. We are proud of the achievements of our team and the capabilities we have built which enable us to further our new drug discovery program. We are delighted to partner with Boehringer Ingelheim in developing treatments that will truly benefit patients in need".

Dr. Raj Kamboj, President of Lupin's Novel Drug Discovery and Development (NDDD) stated, "The success of our second NDDD program in Oncology has added to our confidence in bringing highly differentiated and best-in-class innovation from India for patients globally. Carrying forward our founder, Dr. Desh Bandhu Gupta's dream in shaping true innovation, we have delivered a novel treatment from conceptualization to clinical stage development with promising results that can be a potential combination treatment for precision oncology."

The collaboration has a strategic goal to focus on patients with gastrointestinal or lung cancers defined by KRAS mutations, sub-populations that currently need more effective therapeutic options. KRAS mutations occur in 1 in 7 of all human metastatic cancers making it the most frequently mutated cancer-causing gene, with mutation rates of more than 90 percent in pancreatic cancers, more than 40 percent in colorectal cancers and more than 30 percent in lung adenocarcinomas. Preclinical data has shown that the combination of Boehringer Ingelheim's novel KRAS inhibitors with MEK inhibitors results in increased anti-tumor activity based on their complementary mechanisms of action in keeping KRAS-driven cancers in check.

Lupin's MEK inhibitors developed as part of its oncology pipeline have shown pre-clinical activity as a single agent as well as in combination. Furthermore, they have also shown early clinical benefit in a small subset of patients. Lupin's Novel Drug Discovery and Development team is focused on building a pipeline of highly differentiated and innovative new chemical entities in the therapeutic areas of oncology, immunology and metabolic disorders. Lupin's NDDD activities were started with the vision to use cutting-edge research in bringing novel molecules that address unmet medical needs in multiple therapeutic areas to market globally.

Lupin will receive an upfront payment of \$20 million and potential additional payments for successful achievement of defined clinical, regulatory and commercial milestones for a total deal value of more than \$700 million. Additionally, Lupin will be entitled to receive double-digit royalties on the sales of the product.