Imanova Ltd.

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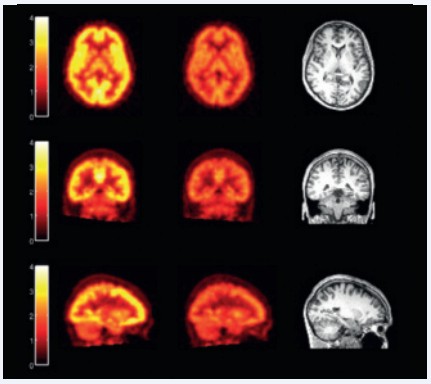
Imanova has its eye on taking imaging beyond the brain

The London-based translational research company is pioneering the development of innovative imaging biomarkers to enhance efficiency and reduce risk in the development of drugs for therapeutic areas such as inflammation and respiratory disease.

The cost of developing a prescription drug that gains market approval is now estimated at $2.6 billion. However, only one in ten novel therapeutics entering clinical trials obtains approval by the U.S. Food and Drug Administration. The combination of the skyrocketing cost of bringing a new drug to market and the substantial risk of failure underscores the strong need for innovative strategies to ensure that only the best candidate molecules progress to later stages of drug development.

Imanova is on a mission to address this growing need by developing novel imaging biomarkers that can provide invaluable information on a drug candidate at early stages of clinical development. Using the noninvasive imaging techniques positron emission tomography (PET) and magnetic resonance imaging (MRI), the company can visualize and quantitate the interactions between a drug candidate and its target in the body, characterizing the drug's mechanism of action at the molecular level. This information can be used to aid decision making early in the drug development process, either supporting further development of promising compounds or discouraging additional investment of time and money in compounds that are likely to fail.

Imanova has the state-of-the-art technology and skills to attach a radioisotope to a drug candidate or a target-specific tool compound, which researchers can then use in early phase clinical studies to generate quantitative data on tissue distribution or target engagement using PET imaging, respectively. The ability to characterize behavior of drug candidates at a tissue level *in vivo* to determine whether they reach their intended site of action in the body at therapeutically relevant levels provides a unique advantage and, together with knowledge of toxicity, can help to define the therapeutic window and optimize dose selection for later proof-of-concept studies. Imaging biomarkers can also be used for early detection of disease, patient stratification and assessment of treatment response.



MRI and PET images of a human brain. The images on the left depict [11C]CIMBI-36 binding in a healthy brain, and the images in the middle column reflect [11C]CIMBI-36 binding after blockade of the 5-HT2A sites by risperidone. The difference between the two sets of images constitutes the 5-HT2A receptor–related binding in the healthy brain. The rightmost column depicts anatomical MRI of the same subject's brain.

This innovative technology allows researchers and companies to gain real insights into the action of each drug in humans earlier in the development process, which can reduce risk and ensure that R&D resources are used efficiently and effectively. "Used in the right way, imaging can considerably shorten the period of early clinical research and reduce the risk of moving into proof-of-concept studies and beyond," said Imanova's CEO, Kevin Cox. "As most drugs fail around this stage, improving success rates by just a small amount can save a company millions of dollars in abortive clinical trials."

Driving innovation in imaging

Imanova was formed in 2011 as an alliance between the United Kingdom's Medical Research Council, Imperial College London, King's College London and University College London. With one of the top clinical imaging facilities in the world and access to internationally renowned scientists and clinical research staff, Imanova offers the skills and resources necessary for end-to-end imaging support in the drug development process. The company works with clients and partners to develop novel biomarkers to meet their specific needs, design and conduct preclinical and clinical studies, and provide analysis and consulting services to optimize the use of imaging data.

"We have all the technology, equipment, laboratories, staff and compounds physically housed in our facility, so the key thing is that we can manage the program end to end in an efficient and effective way," Cox said. "Moreover, we have experience in a broad range of diseases, and through our academic links we have access to a wide variety of disease experts and patients for clinical studies. Our alliance with three world-class institutions in London provides unrivalled capabilities to facilitate the drug development process."

So far, Imanova has developed more than 15 imaging biomarkers to good manufacturing practice (GMP) standards, has completed more than 50 clinical studies and is engaged in more than 200 studies all together. In recent years, the translational research company has moved beyond the brain to offer unprecedented molecular imaging tools for therapeutic areas such as oncology, inflammation and respiratory diseases. The development of imaging biomarkers for organs other than the brain has lagged far behind that for the central nervous system (CNS) owing to a variety of technical challenges, which has limited the ability of scientists to gain a detailed understanding of drug-target interactions and molecular mechanisms of action in non-CNS diseases.

Capitalizing on its deep expertise in imaging sciences, strong collaborations with academia and expanding focus on the applications of imaging, Imanova has begun to address these challenges. An example of this is the ongoing development of a novel biomarker, branded IMA-FIB, for imaging fibrosis in a number of diseases. Having yielded promising preclinical results, this tracer is now being applied in clinical studies. In addition, the company is currently developing biomarkers for inflammatory diseases such as chronic obstructive pulmonary disease, rheumatoid arthritis and inflammatory bowel disease.

Oncology also represents an exciting opportunity for extending this technology. The imaging tools currently available simply locate tumors in the body without providing a detailed understanding of the disease process at the molecular level. Imanova is developing novel imaging agents that give a detailed picture of tumor metabolism, as well as other molecular processes in the tumor cell.

"We are on a mission to establish a strong pipeline of imaging tools, both internally and in collaboration with pharmaceutical and biotechnology companies, to exploit their untapped potential in organs beyond the brain," Cox said. "In the end, these collaborative efforts will undoubtedly increase productivity, reduce waste and drive innovation in the drug development process."

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