Radiopharmaceutical therapy offers precision approach to cancer treatment with targeted radioisotopes for tumours

Radiopharmaceutical therapy is one of the fastest-growing treatment modalities for solid tumours, presenting exciting growth opportunities for BMS in the coming years. Expanding into new disease areas poses challenges, including understanding unique biological mechanisms, navigating regulatory landscapes, and adapting to a rapidly changing environment. Through the acquisition of RayzeBio, BMS now leads in RPT development, with several potential first- or best-in-class programmes.

Mumbai: Dr Samit Hirawat, MD, Executive Vice President, Chief Medical Officer, and Head of Development at Bristol Myers Squibb, spoke with ETPharma's Prabhat Prakash about how AI and ML are enhancing clinical trial design and data analysis. Dr Hirawat also discussed how differentiated research platforms allow BMS to tailor approaches for specific therapeutic needs, expediting the discovery of patient-centric therapies. He shared how the acquisition of RayzeBio aligns with the company's vision to advance innovative cancer treatments, positioning RPT as both a diagnostic and therapeutic option for cancer patients. Edited Excerpts:

How are artificial intelligence (AI) and machine learning (ML) improving clinical trial design and data analysis? How does digital innovation accelerate new drug development? What impact does this technology integration have on regulatory processes and patient outcomes?

We're leveraging AI and machine learning at BMS to transform research and drug development. By creating a complete picture of diseases and patient profiles through rich datasets and predictive methods, we're able to accelerate and optimise clinical trials.

AI aids in selecting key trial locations by analysing data to pinpoint areas with high patient concentrations for specific diseases. With the power of cloud computing and clinical trial simulation tools, we can quickly explore design parameters, enhance data accuracy, and facilitate collaboration, allowing our teams to focus on innovative and patient-centric research.

Robotics and intelligent process automation, driven by our Digital Protocol Solution, streamline trial operations, automate reporting, and transform regulatory interactions. Virtual clinical trials, using simulations, reduce patient burden and accelerate trial planning.

We're also using AI to analyse real-world anonymised data and simulate data from underrepresented groups, improving diversity in clinical trials and treatment outcomes for underserved communities. From a regulatory standpoint, we ensure ethical and responsible AI use, meeting both internal policies and regulatory standards. Our advanced machine-learning techniques reveal hidden patterns in complex data, accelerating safer and more effective drug development.

> For patient outcomes, AI and ML enhance enrollment, assess meaningful endpoints, and improve therapy effectiveness, ensuring faster market access for tailored treatments. This patient-centric approach, especially for underserved communities, is strengthened through AI-driven decision-making, enhancing trial quality and scale.

What are the advantages of having differentiated research platforms, and how do they expedite the discovery of patient-centric therapies?

Our differentiated research platforms allow us to tailor therapeutic approaches, expediting patient-centric therapy discovery. BMS leads in cell therapy, with two approved treatments and continued advancements in manufacturing. We're exploring dual-targeting CARs, allogeneic approaches, and new targets in immunology, focusing on diseases like lupus and multiple sclerosis.

In protein degradation, we're building a robust pipeline with assets like molecular glues and antibody-drug conjugates, with multiple assets in various development stages. This platform aims to produce new investigational drugs annually, addressing a wide array of diseases.

Radiopharmaceutical therapy (RPT) provides a precision approach by delivering targeted radioisotopes directly to tumours. With RayzeBio, BMS leads in RPT development, exploring therapies for cancers, including GEP-NETs, small-cell lung cancer, and hepatocellular carcinoma.

What challenges and opportunities do you encounter when entering new disease areas?

Tackling complex diseases requires navigating unique biological mechanisms, regulatory landscapes, and external environments, but it also brings opportunities for innovation and broader patient impact. Leveraging technology and automation reduces complexity, improves consistency, and enhances our ability to deliver effective treatments.

How is the company using targeted protein degradation, CAR T-cell therapies, and radiopharmaceuticals to address previously untreatable conditions?

BMS's diversified pipeline includes targeted protein degradation, cell therapy, and radiopharmaceuticals. Our two approved CAR T cell therapies have distinct targets, and we're exploring CAR T therapy's potential for resetting immune systems in autoimmune diseases, such as lupus.

In targeted protein degradation, our platform targets disease-causing proteins for degradation. By binding proteins and tagging them for breakdown, we're addressing conditions once considered undruggable, from cancer to autoimmune diseases. Our approach uses three modalities: molecular glues (CELMoD agents), ligand-directed degraders (LDDs), and degrader antibody conjugates (DACs), expanding opportunities for breakthroughs in blood cancers, solid tumours, immune-mediated diseases, and neurological disorders.

How does the acquisition of RayzeBio align with BMS's vision for innovative cancer treatments?

The acquisition of RayzeBio aligns with our vision for advancing innovative cancer treatments. RPT is uniquely positioned to serve as both a diagnostic and therapeutic, offering a precision approach by delivering radioisotopes to tumours, sparing healthy cells. As one of the fastest-growing treatment modalities for solid tumours, RPT unlocks growth opportunities for BMS. RayzeBio's expertise will accelerate our preclinical and clinical programmes, benefiting patients worldwide.

India has the potential to become a global hub for clinical trials; how do you see this shaping the future of healthcare in India? What steps are being taken to increase access to such studies?

India's potential as a global clinical trial hub is significant, with its diverse patient populations and cost-effective research environment. We're investing in infrastructure, collaborating with local stakeholders, and expanding our clinical trials in India—currently over 20 trials, with plans to double this in the next two years.

Our Hyderabad innovation hub plays a pivotal role, with around 2,000 employees expanding BMS's drug development, IT, and digital capabilities. Leveraging Hyderabad's innovation ecosystem and AI applications, the hub supports clinical trials and drug development, advancing BMS's vision of transforming lives through science.

How do you balance developing first-in-class and best-in-class medicines across therapeutic areas?

We aim to redefine care standards in haematology, oncology, cardiovascular disease, and neuroscience by focusing on unmet medical needs and developing first- and best-in-class medicines. Our strategy includes accelerating drug development through digital innovation, differentiated research platforms, and partnerships to bring life-changing treatments to patients globally.

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