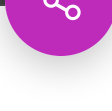




Science

Shaping the future of drug development with space-based protein crystallization



December 03, 2020

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Bristol Myers Squibb researchers follow the science wherever it leads – even into space.

The company is set to send a selection of biologics medicines and investigational assets to the International Space Station to observe how they grow crystals in near-zero gravity. The unique study opportunity could inform future directions in drug development and manufacturing, and may someday yield important benefits to patients.

Biologics are protein-based medicines derived from living cells. Their final form is typically a solution patients receive by intravenous infusion. But what if these medicines could be made in crystal form? A crystallized therapeutic could in theory have greater stability and a more concentrated dosing strength. For patients, that could be the difference between needing a quick injection or needing to travel for lengthy, periodic infusions. For drug makers, the science of protein crystallization could revolutionize how biologics drugs are developed and manufactured, changing everything from the time it takes to bring products to market to the space needed to store them on shelves.



Three members of the company research team were on site at Kennedy Space Center in Florida to prepare the experiment for launch. From left: Senior Research Investigator II Matt Pokross, Robert Garmise, associate director, Materials Science & Engineering; and Research Investigator II Michael Little.

Molecular crystal growth in near-zero gravity

While it’s much more than science fiction, the science still has a way to go. By studying how these molecules crystalize in space, scientists expect to gain new insights into how to advance this research into protein crystallization on Earth.

Just as a jar of honey stored in a refrigerator will form crystals, certain conditions can coax the crystallization of biologics, and micro-gravity is one of

them.

“In space, the physics are different. The forces acting upon the crystal molecules are different,” said Robert Garmise, associate director in Bristol Myers Squibb’s Materials Science & Engineering group, and leader of company’s space station research project. “You can get more ordered, higher-quality crystals, more uniform in size and shape, and larger than what you could grow on Earth.”

The experiments will be conducted by a NASA scientist onboard the orbiting laboratory following protocols that Garmise’s team developed and validated at company research labs in New Jersey – work that was halted for a time by the COVID-19 pandemic.

Research Investigator II Michael Little in the Drug Product Development group helped design those protocols. Samples of the three proteins to be studied will be placed in crystallization plates that have numerous, tiny wells. The NASA scientist will set up the plates in a space station lab, combine the proteins with reagents that promote crystal growth, and document their growth with a microscope imager over 30 days.

“We built an internal crystallization screening workflow in our lab in New Brunswick,” said Little. “One of the things this project has displayed to me is how Bristol Myers Squibb supports innovative thinking that could improve the drug development process and patient experiences.”

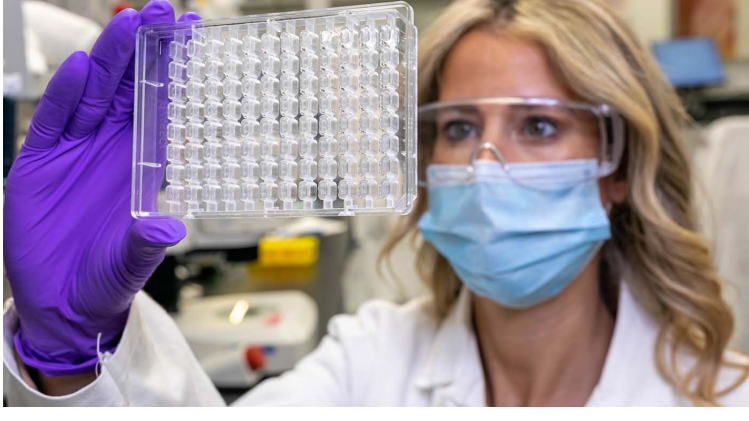
Providing future directions in drug development

The study of protein crystallization in microgravity is a subset of a broader company initiative researching ways to stabilize biologic medicines in a solid state. Other techniques, including spray freeze-drying, are being explored and offer a variety of potential benefits.

Before biologics medicines are put into their final dosing form, they are manufactured in bulk and kept frozen at minus 20 degrees Celsius. Stabilizing this bulk drug substance in a solid state could allow for higher storage temperatures. It could also substantially decrease a medicine’s mass and volume, reducing or eliminating the water that typically forms 80 to 90 percent of a drug’s solution. Such changes could create major efficiencies across the biopharmaceutical supply chain.

The experiments in space will build on and advance these earthbound efforts. In addition, the potentially higher-quality crystals obtained in microgravity are expected to reveal more about the structures of these proteins – data that will be valuable regardless which stabilization technique is pursued.

“Our team’s involvement with these experiments is an incredible opportunity to gather scientific insights for our company to better help patients, and to advance the field of protein crystallization in the discovery, development and delivery of new medicines,” said research team member and Associate Research Scientist, Protein Crystallization, Christina Cuttitta. “The information that we hope to obtain in these microgravity experiments will serve as a basis for better processes on Earth.”



Research team member and Associate Scientist Christina Cuttitta examines a crystallization plate.



A patch Bristol Myers Squibb developed with the International Space Station Research Lab commemorates the mission. The letters MCRM refer to Monoclonal Crystal Research in Microgravity.

A long-awaited countdown

The company’s crystallization experiments are scheduled to be ferried to the International Space Station by NASA’s commercial cargo provider SpaceX on Dec. 5 on a rocket carrying supplies and equipment for a range of scientific investigations. For the research team, it’s a moment that represents the culmination of efforts that began in the summer of 2018 when the company responded to request for proposals from the

International Space Station’s Center.

“I never could have imagined I’d have a chance to be a part of something like this,” said project team member and Senior Research Investigator II Matt Pokross. “It’s one of the advantages of working in a company that really fosters innovation and creative ways of thinking about things that you can find opportunities like this.”

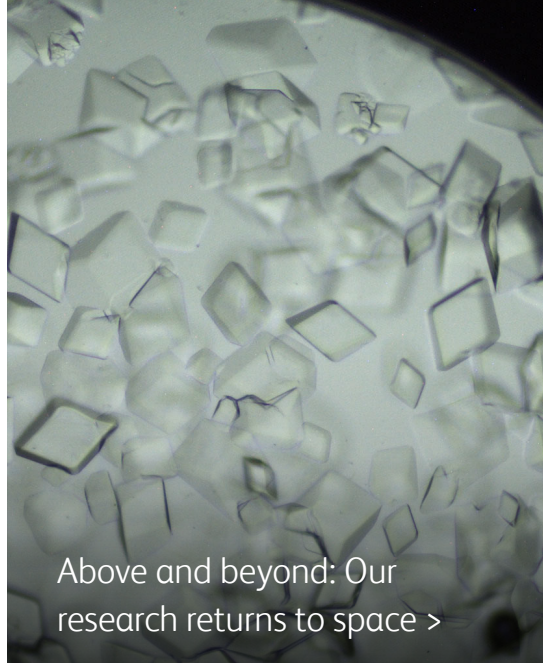
About Bristol Myers Squibb

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. As global citizens, we work sustainably and responsibly to create a positive impact in the communities where we live and work.

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