

Healthcare industry BW

Rentschler Biopharma contributes to manufacturing of COVID-19 mRNA vaccine

Joining forces against SARS-CoV-2

Rentschler Biopharma SE, a leading global contract development and manufacturing organization (CDMO) for biopharmaceuticals, today announced an agreement to serve as CDMO partner for BioNTech. As an initial project, Rentschler Biopharma will be responsible for key aspects of cGMP (current good manufacturing practice) drug substance manufacturing of BNT162b2, the mRNA-based vaccine against SARS-CoV-2 that is being developed by Pfizer and BioNTech, and is currently in a global Phase 3 clinical trial.

Under the agreement, Rentschler Biopharma will be responsible for downstream processing to provide highly purified drug substance. Process and product-related impurities will be effectively removed from the intermediate pool, which has been previously derived from mRNA synthesis. This is an important step in ensuring the safety and tolerability of a vaccine for use in humans, while at the same time maximizing the amount of mRNA harvested from the initial production process. Rentschler Biopharma will produce purified drug substance at its headquarters in Laupheim, Germany.

Dr. Frank Mathias, CEO of Rentschler Biopharma, said: "We are honored to contribute to BioNTech's 'Project Lightspeed' and their work in developing this highly innovative mRNA vaccine. To tackle the COVID-19 pandemic, it is critical to bring high-quality, safe and effective vaccines to the public quickly and on a large scale. At Rentschler Biopharma, we feel it is important to do our part in combatting this virus. As a cGMP service provider with more than 40 years of proven manufacturing expertise, we are well suited to work with BioNTech to make their ground-breaking science a medical reality and will work tirelessly to this end."

BioNTech and Rentschler Biopharma will use an innovative business model that is well suited for novel, urgently needed technologies and allows maximum flexibility to address BioNTech's development and manufacturing requirements. In addition to large-scale production services for the COVID-19 vaccine, the agreement also provides for small-batch manufacturing of BioNTech's other RNA programs for use in clinical trials.

Federico Pollano, SVP Global Business Development of Rentschler Biopharma, added: "We are excited to have the opportunity to work with BioNTech on this urgent project, as well as over the long term. A critical success factor in all the projects we take on at Rentschler Biopharma is close collaboration with our clients. Working in partnership with BioNTech, we determined that the best way to address their COVID-19 vaccine drug substance manufacturing needs was to establish a dedicated mRNA production suite for them in our Laupheim facility. This approach ensures capacity, staff and equipment are ready when needed without interruption of other ongoing projects at our site. It is also an approach that is quickly and easily scalable to meet future demands."

Press release

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Source: Rentschler Biopharma SE

Further information

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