Biontech/Pfizer (Comirnaty®): Spät, aber immerhin

Liebe Kolleginnen, liebe Kollegen,

heute hat die Europäische Arzneimittelagentur (EMA) dem Antrag von Biontech/Pfizer stattgegeben, den aufgetauten, aber noch nicht mit Kochsalz verdünnten Impfstoff Comirnaty® 31 Tage statt bislang nur fünf Tage lang im Kühlschrank (2–8° C) aufzubewahren.

Innerhalb dieser 31-Tage-Periode ist der Transport für eine Gesamtzeit von 12 Stunden möglich.

▶ Die im letzten Benefit angesprochene Möglichkeit, applikationsfertige Spritzen (0,3 ml) bei bei 2–25° C für bis zu 6 Stunden zu transportieren und zu verabreichen, bleibt von dieser neuen Regelung unberührt.

Mit dieser Neujustierung wird die Handhabung des Impfstoffs in der Praxis erheblich erleichtert. Warum diese Haltbarkeitsdaten erst jetzt, fast ein halbes Jahr nach Zulassung, erscheinen, bleibt mit verborgen. (Die Mitteilung des Mainzer Unternehmens ist dieser Nachricht angehängt.)

Herzliche Grüße

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Update on Stability of COMIRNATY®: Longer Storage Possible

May 17, 2021

On May 17, 2021, the European Medicines Agency (EMA) has approved a change to the existing storage conditions.

The thawed, undiluted COVID-19 vaccine can be stored at fridge temperatures of 2 °C to 8 °C for one month (31 days), instead of five days at fridge temperatures as previously indicated.

Within this 31-day-period, transport of the thawed, undiluted vials is still possible for a maximum of 12 hours in total. The shelf life of the diluted vaccine does not change and is stable for 6 h at 2-30 °C from the time of dilution and must be administered within this time.

The change of the storage conditions is based on new data from stability studies that confirmed the product quality for 31 days. The formulation remained unchanged. The extended storage period is effective immediately and accounts for all currently available and future batches. The companies have already submitted a similar request to the U.S. Food and Drug Administration (FDA) and plan to request additional amendments with other regulatory authorities worldwide.

About BioNTech
Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de.

BioNTech Forward-looking Statements
This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including a potential second booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); the potential of BNT162b2 for adolescents 12 to 15 years of age, evaluation of BNT162b2 in children 6 months to 11 years old, anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply); our expectations regarding the potential characteristics of BNT162b2 in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; the risk that demand for any products may be reduced or no longer exist; the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimates for 2021; and challenges related to public vaccine confidence or awareness. Any forward-looking statements in this press release are based on BioNTech's current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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