



January 23, 2023

22nd Century Group (XXII) Announces Filing of U.S. DMF (Drug Master File) for CBD API; New Global Sales, Marketing and Distribution Agreement with Transo-Pharm for Cannabinoid APIs

Partnership Will Provide Pharmaceutical Grade Cannabinoid Active Ingredients to the Largest Pharmaceutical and Consumer Goods Names in the Industry

BUFFALO, N.Y., Jan. 23, 2023 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (Nasdaq: [XXII](#)), a leading biotechnology company dedicated to improving health with reduced nicotine tobacco, hemp/cannabis and hops advanced plant technologies, today announced filing of a U.S. Drug Master File (DMF) to the US Food & Drug Administration (FDA) for cannabidiol (CBD) API from GVB Biopharma, a 22nd Century Group Company. The submission (DMF 037727) demonstrates 22nd Century Group's absolute commitment to supplying high quality pharmaceutical grade API to the pharmaceutical industry and OTC markets.

Said James A. Mish, chief executive officer of 22nd Century, "GVB Biopharma is widely recognized for the quality and consistency of its Cannabinoid extracts and ingredients. We are now leveraging these capabilities with our DMF filing to meet the increasing regulatory demands of the supplements markets, and in parallel it expands our reach to the pharmaceutical and OTC markets, where consistently regulated high quality ingredients are a requirement. Our compliance infrastructure will ensure that our customers consistently receive API that meets the appropriate quality standards."

Additionally, 22nd Century and GVB Biopharma have entered into an agreement with Cannabinoid API Solutions (CAS) and Transo-Pharm for global sales, marketing and distribution of GVB's Cannabinoid APIs. With more than 35 years of industry experience as a leading global supplier of pharmaceutical grade APIs, Transo-Pharm is a well-established supplier and distributor of pharmaceutical APIs to a broad portfolio of branded and generic finished drug product manufacturers, including more than 75 current active ongoing development programs. Transo-Pharm is partnered with an extensive range of reputable multinational pharmaceutical companies, all of which will have immediate access to GVB's cannabinoid APIs.

"The partnership with Transo-Pharm will accelerate opportunities to supply our APIs to the largest and most innovative pharmaceutical and consumer goods manufacturers in the world," said Mish. "We estimate the Cannabinoid Derived Pharmaceutical market to be worth \$1 billion in 2022 and growing, a trend we see accelerating as new entrants continue join the market. This partnership immediately provides us with the channel access and reach to support pharmaceutical programs worldwide as well as securing new opportunities in over-the-counter and consumer packaged goods spaces. Our regulated pharmaceutical grade ingredients supply chain will provide for the highest levels of quality, consistency and compliance across our entire customer base."

About Transo-Pharm

Founded in 1987 and based in Germany and the US, Transo-Pharm has established a global reputation as a trusted supplier of active pharmaceutical ingredients (APIs). Transo-Pharm successfully connects suppliers and customers utilizing our experience, industry knowledge, marketing expertise and logistics capabilities. For more information, please visit <https://www.transopharm.com/tpusa.html>.

About 22nd Century Group, Inc.

22nd Century Group, Inc. (Nasdaq: [XXII](#)) is a leading biotechnology company focused on tobacco harm reduction, reduced nicotine tobacco and improving health and wellness through plant science. With dozens of patents allowing it to control nicotine biosynthesis in the tobacco plant, the Company has developed proprietary reduced

nicotine content (RNC) tobacco plants and cigarettes, which have become the cornerstone of the [FDA's Comprehensive Plan](#) to address the widespread death and disease caused by smoking. The Company received the first and only FDA Modified Risk Tobacco Product (MRTP) authorization of a combustible cigarette in December 2021. In tobacco, hemp/cannabis and hop plants, 22nd Century uses modern plant breeding technologies, including genetic engineering, gene-editing, and molecular breeding to deliver solutions for the life science and consumer products industries by creating new, proprietary plants with optimized alkaloid and flavonoid profiles as well as improved yields and valuable agronomic traits.

Learn more at xxiicentury.com, on [Twitter](#), on [LinkedIn](#), and on [YouTube](#).

Learn more about VLN® at tryvln.com.

Cautionary Note Regarding Forward-Looking Statements

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. Forward-looking statements typically contain terms such as “anticipate,” “believe,” “consider,” “continue,” “could,” “estimate,” “expect,” “explore,” “foresee,” “goal,” “guidance,” “intend,” “likely,” “may,” “plan,” “potential,” “predict,” “preliminary,” “probable,” “project,” “promising,” “seek,” “should,” “will,” “would,” and similar expressions. Actual results might differ materially from those explicit or implicit in forward-looking statements. Important factors that could cause actual results to differ materially are set forth in “Risk Factors” in the Company’s Annual Report on Form 10-K filed on March 1, 2022, and in the Company’s Quarterly Report filed on August 9, 2022. All information provided in this release is as of the date hereof, and the Company assumes no obligation to and does not intend to update these forward-looking statements, except as required by law.

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