

# News Release

## BAT progresses COVID-19 candidate vaccine into Phase I human clinical trials

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- Investigational New Drug application approved by the FDA for COVID-19 candidate vaccine, allowing BAT to progress into a Phase I clinical trial in adult volunteers
- Vaccine candidate created using innovative plant-based technology
- Vaccines manufactured using BAT's vaccine platform have the potential to be stable at room temperature which could offer significant advantages
- Study demonstrates BAT's commitment to delivering science and innovation that build *A Better Tomorrow*

BAT's US Bio-tech arm, Kentucky BioProcessing (KBP) today announced plans to commence a Phase I first-time-in-human study of its COVID-19 vaccine candidate following approval of its Investigational New Drug application by the U.S. Food and Drug Administration (FDA). Enrolment for the study is expected to begin shortly.

The COVID-19 vaccine candidate (KBP-COVID-19; NCT04473690) will become one of a number of potential vaccines to have progressed beyond pre-clinical testing. The study is designed to enroll a total of 180 healthy volunteers who will be divided into two age cohorts, age 18-49 and age 50-70. Each group will then be subdivided into low and high dose treatment groups (N~45) and randomised 2:1 to receive either the low dose (15 µg KBP-COVID-19 vaccine + 0.5 mg adjuvant) or placebo, or high dose (45 µg KBP-COVID-19 vaccine + 0.5 mg adjuvant) or placebo. Results from the study are expected mid-2021 and, if positive, would allow for continued progress into a Phase 2 study, subject to regulatory approval.

The candidate vaccine has been developed using KBP's innovative fast-growing plant-based technology. This unique approach has a number of possible advantages, including the rapid production of the vaccine's active ingredients in around 6-weeks, compared to several months using conventional methods. The candidate vaccine also has the potential to be stable at room temperature, which could be a significant advantage for healthcare systems and public health networks worldwide. If successful, the speed of production of the active ingredients has the potential to reduce the time between identifying new viruses and strains, and vaccine development and deployment to those who need it.

KBP is conducting and recently completed enrolment for a Phase I clinical study of its quadrivalent (four-strain) influenza vaccine candidate (KBP-V001; NCT04439695), which uses the same nicotiana benthamiana plant-based technology platform.

**Dr David O'Reilly, BAT's Director of Scientific Research said:**

"Moving into human trials with both our COVID-19 and seasonal flu vaccine candidates is a significant milestone and reflects our considerable efforts to accelerate the development of our emerging biologicals portfolio. It is our unique

plant-based vaccine technology, which acts as a fast, efficient host for the production of antigens for a variety of diseases, that has enabled us to make this progress and respond to the urgent global need for safe and effective treatments and vaccines.

“This is part of our ongoing commitment to innovation and science, which are fundamental to our business. As a company committed to building *A Better Tomorrow*, we are proud to play our part in the global fight against this virus and – hopefully – we can contribute to the solution.”

With both vaccines reaching these important milestones, the science around tobacco plant-based vaccine development and the unique platform continue to gain momentum.

## Enquiries

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## Notes to Editors

The COVID-19 candidate vaccine in development uses KBP’s proprietary, fast-growing plant technology which has several potential advantages over conventional vaccine production technology:

- Tobacco plants cannot host pathogens which cause human disease
- Production may be faster because the elements of the vaccine accumulate in tobacco plants quickly – 6 weeks in tobacco plants versus several months using conventional methods
- The vaccine formulation being developed has potential to be stable at room temperature, unlike many other conventional vaccines which often require refrigeration

BAT/KBP’s candidate COVID-19 vaccine, KBP-COVID-19, is not currently approved or licensed for use anywhere in the world.

## About Kentucky BioProcessing (KBP)

BAT-owned KBP is located in Owensboro, KY., where it began operations in 2006. In January 2014, KBP was acquired by and became an independently operated, wholly-owned subsidiary of Reynolds American Inc. (RAI), owned by BAT. KBP continues to house its large, multilevel indoor plant-growth space, as well as its research and production laboratories, clean rooms and manufacturing operations in Owensboro.

KBP develops and executes processes to transform tobacco plants into “biomanufacturing factories” that efficiently produce complex proteins they would not otherwise produce. With the right commercial partner, the company can grow, harvest and process as many as 3 million protein-producing plants in a production cycle that typically takes about 6 weeks – compared with many months using traditional biomanufacturing methods.

The company uses licensed and proprietary technologies to temporarily encode tobacco plants with the genetic instructions to produce specific target proteins. The plants are grown in an automated, climate-controlled environment that can be adjusted to optimize their production of a protein of interest.

## Forward looking statements

This communication contains certain forward-looking statements, including “forward-looking” statements made within the meaning of Section 21E of the United States Securities Exchange Act of 1934. These statements are often, but not always, made through the use of words or phrases such as “believe,” “anticipate,” “could,” “may,” “would,” “should,” “intend,” “plan,” “potential,” “predict,” “will,” “expect,” “estimate,” “project,” “positioned,” “strategy,” “outlook,” “target” and similar expressions. These include statements regarding our intentions, beliefs or current expectations concerning, amongst other things, our results of operations, financial condition, liquidity, prospects, growth, strategies and the economic and business circumstances occurring from time to time in the countries and markets in which the BAT Group operates.

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No statement in this communication is intended to be a profit forecast and no statement in this communication should be interpreted to mean that earnings per share of BAT for the current or future financial years would necessarily match or exceed the historical published earnings per share of BAT.

Additional information concerning these and other factors can be found in BAT’s filings with the U.S. Securities and Exchange Commission (“SEC”), including the Annual Report on Form 20-F filed on 26 March 2020 and Current Reports on Form 6-K, which may be obtained free of charge at the SEC’s website, <http://www.sec.gov>, and the Company’s Annual Reports, which may be obtained free of charge from the British American Tobacco website [www.bat.com](http://www.bat.com).