pHOXBIO ANNOUNCES BREAKTHROUGH CLINICAL TRIAL RESULTS CONCLUDING PROPHYLACTIC NASAL SPRAY PREVENTS INFECTION FROM SARS-CoV-2.

- pHOXWELL significantly reduced SARS-CoV-2 infection by 63% with tolerability comparable to placebo in high-risk population of healthcare workers

- Novel self-administered nasal spray designed to augment existing preventive measures for SARS-CoV-2, including PPE and vaccines

- Regulatory filing initiated in India for SARS-CoV-2 prevention claim

- Company exploring strategic alternatives to make product accessible in India and markets worldwide to help combat ongoing COVID-19 pandemic and future disease outbreaks

London and New York, September 22, 2021 — pHOXBIO Ltd. today announced results from a randomized, double-blind, placebo-controlled clinical trial which demonstrate that pHOXWELL, its novel prophylactic nasal spray, prevented infection from SARS-CoV-2, the virus that causes COVID-19. In a pivotal Phase 2/3 clinical study, there were 63% fewer SARS-CoV-2 infections in high-risk healthcare workers given pHOXWELL compared to placebo (p=<0.0001).

pHOXWELL is a self-administered prophylactic nasal spray designed to offer a variant-agnostic mechanism of action that provides a robust defence to inhibit the infection processes of SARS-CoV-2. It is designed to be effective against other airborne respiratory viruses. The product offers 6-8 hours of protection with just two sprays per nostril, per application, and can be applied whether in the workplace, at home or “on-the-go”.

Company Chairman, Professor Rakesh Uppal, Professor of Cardiovascular Surgery at Queen Mary University of London and Director of Barts Life Sciences, says “pHOXWELL presents a significant breakthrough. We now have an effective tool, previously missing, to fight this pandemic. Vaccination, while absolutely essential, is not 100% effective and it is still possible to become infected by, and transmit, the virus that causes COVID-19. pHOXWELL is designed to offer extra protection to vaccines and PPE, as the spray inhibits SARS-CoV-2 from infecting the nasal mucosa, which is the primary entry point into the body. pHOXWELL’s efficacy is likely to be maintained with future mutations in the virus”.

Study Design and Results

The study was a double-blind, randomized, placebo-controlled study to assess the efficacy and safety of pHOXWELL nasal spray in the prevention of SARS-CoV-2 infection in high-risk healthcare professionals in India. The trial was carried out during the peak surge of the highly infectious Delta variant in India in April to July 2021. The study was designed following approval by the appropriate
regulator. The primary end point was the percentage of subjects who test positive for SARS-CoV-2 on IgGS (spike protein specific) testing over the 45 days of the study. Secondary end points included efficacy, safety and tolerability measures.

The primary end point showed that 13.1% of subjects were IgGS positive in the pHOXWELL arm versus 34.5% in the placebo arm (p= <0.0001). This result shows that pHOXWELL has a significant prophylactic effect versus SARS-CoV-2 infection when compared to placebo. These highly statistically significant results were consistent across the two sites which recruited subjects (Site 1 17.4% vs 54.6%, p=<0.0001; Site 2 11.1% vs 23.9%, p=0.0015) and sex (male 13.6% vs 36.6%, p=<0.0001; female 12.1% vs 31.2%, p=0.0013).

The secondary end point looking at subjects experiencing clinical symptoms, also shows significant results in favour of pHOXWELL, with only 17.6% of subjects who experienced infection in the pHOXWELL arm having clinical symptoms versus 34.6% in the placebo arm (p=<0.0001). These results were consistent across sex (male 15.3% vs 31.8%, p=0.0001; female 21.7% vs 39%, p=0.0048) and age groups (18-35 26.5% vs 43.6%, p=0.0091; 36-65 19.4% vs 36.9% p=0.0018; 65+ 6.9% vs 33.3%, p=0.0407).

User acceptability end points were positive, with an overall positive experience maintained across the study. pHOXWELL also exhibited an excellent safety profile.

648 subjects completed the study. The mean age was 40.8 years. 63.3% of subjects were male and 36.7% female. All subjects were over 18, unvaccinated, demonstrated not to be infected with SARS-CoV-2 at the time of entry (RT-PCR), and not to have had any previous infections (IgG Spike protein negative). They were treated three times a day with active or placebo prior to any possible exposure situation to SARS-CoV-2 over 45 days. Subjects were regularly tested by RT-PCR for SARS-CoV-2 infection, 556 had IgGS testing at the last visit and potential symptoms and adverse events were recorded. A technical issue during the study caused RT-PCR testing not to work for the infection end point for all subjects, hence the use of IgGS testing.

Company Seeking To Deliver Benefits to Society
pHOXBIO and its parent company, Raphael Labs, will now initiate a regulatory filing to support a SARS-CoV-2 prevention claim with the appropriate regulator, based on the clinical trial data. This will allow for production and distribution of pHOXWELL in India initially, with further territories intended to follow as a prophylaxis against SARS-CoV-2 infections.

Professor Uppal, said “there is a pressing need globally for a prophylactic nasal spray to help prevent infection in areas where vaccination rollout remains inadequate in the face of the tragic human toll of this pandemic. We are confident that our anti-COVID-19 nasal spray, pHOXWELL, will become a vital part of the global armoury to provide an extra defensive shield to tackle the pandemic, and we welcome forming partnerships with governments, NGOs and manufacturers to deliver the preventative benefits of pHOXWELL”.

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Professor Charles Bangham of Imperial College London comments, “If the product is cheap and stable, then, since it is easily administered, it may have the potential to make an important reduction in the incidence of SARS-CoV-2 infection in exposed individuals.”

pHOXWELL is low cost, easy to manufacture, shown to have prolonged stability at room temperature and can be transported globally. It is anticipated its use will be applicable to many populations where vaccination rates remain low and PPE is scarce, particularly for frontline health workers. pHOXBIO is seeking to evaluate opportunities that can help accelerate the delivery of its products’ benefits to society. Interested parties can contact the company at https://phoxbio.com/#/contact.

About pHOXWELL
pHOXWELL is a combination of natural virucides and Vita Raphael, a proprietary solution, which work in concert to prevent viral infection. pHOXWELL is designed to provide additional protection that complements current standards of care in inhibiting the spread of airborne respiratory viruses, including PPE and vaccines. pHOXWELL is virucidal and has been designed to inhibit the infection of other airborne respiratory viruses including common and new strains of coronaviruses, influenzas and rhinoviruses. In vitro testing confirmed that pHOXWELL killed 90% of H1N1 (Influenza) in under 5 minutes.

pHOXWELL offers 6-8 hours of protection with just two sprays per application and can be applied whether at home, at work or “on the go”. pHOXWELL can be used by most people, whether vaccinated or not, and is aimed at adults ages 18 and over.

Airborne Respiratory Viruses & Current Gaps
Viruses are amongst the most infectious and debilitating airborne respiratory pathogens. Even without SARS-CoV-2’s devastating impact, airborne respiratory pathogen spread contributes to respiratory infection and cause around 4 million preventable deaths each year. The ability of vaccines alone to control the spread of airborne respiratory viruses is limited by significant challenges including variable efficacy and challenges faced by emerging variants, global supply demands and shortages in developing countries, and vaccine hesitancy and unsuitability for some.

PPE use can be insufficient, used incorrectly or malfunction and in some areas is poorly available. There is a significant need for an effective and safe prophylactic that complements vaccines and PPE.

About pHOXBIO and Raphael Labs
pHOXBIO is a privately held biopharmaceutical company that is a division of Raphael Labs. The company is developing pHOXWELL and pHOXGEN, two unique solutions targeting prophylaxis of airborne respiratory viruses such as coronaviruses and influenza viruses that cause some of the world’s deadliest communicable diseases. pHOXBIO products represent a scientific breakthrough with the potential to impact public health and strengthen pandemic preparedness by addressing substantial gaps in current control measures.
Raphael Labs is an Irish privately held biopharmaceutical company with a significant UK operation, managing a diverse portfolio of subsidiaries with specific interests in the development and commercialization of Raphael Labs’ proprietary formulation Vita Raphael. Company subsidiaries include pHOXBIO, which addresses respiratory diseases; pHOXMETICS, which addresses cosmeceutical interests; pHOXHEAL, which is focused on wound care; and a research and development arm called pHOXWORX.

Raphael Labs’ scientific leadership team includes Professor Dame Kay Davies, Doctor Lee’s Professor of Anatomy, Emeritus at Oxford University; Professor Steve Davies, Waynflete Professor Emeritus of Chemistry at Oxford University; Alan Dunton M.D., based in Boston; Mr. Goutham K Gorti, FRCS, based in New Jersey; Professor Áine McKnight, Professor of Viral Pathology at the Blizard Institute, Queen Mary University of London; Professor Angela Russell, Professor of Medicinal Chemistry at Oxford University; Dr. Jim Swales, pHOXWELL’s clinical trial lead; Professor Mauro Teixeira, Professor of Immunology, Universidade Federal de Minas Gerais, and Professor Rakesh Uppal, Professor of Cardiovascular Surgery, William Harvey Research Institute, Queen Mary University London, Barts Heart Centre and Director of Barts Life Sciences.

Raphael Labs is supported by Mark Timney, Graeme Bell, and Michael Blash in the United States.

News release ends