

Press release: 2020-09-10

## **BioGaia Pharma secures approval for two clinical trials for its pharmaceutical candidates**

**BioGaia Pharma has received formal approval from relevant authorities to proceed with both of its planned clinical trials. The trials are the next phase in the development of BioGaia Pharma's two pharmaceutical product candidates. The biologics both contain a single strain live microbial as API. Recruitment will start during late 2021.**

The first program BGP014 is for Ulcerative Colitis (UC). UC is a debilitating condition characterised by chronic inflammation in the intestinal tract affecting roughly 2,5 million patients in Europe and the US alone. There is no cure for UC and patients need life-long treatment prescribed according to the severity of the disease. The primary goal in UC therapy is to induce and maintain remission. First line standard of care is effective for a proportion of patients with few side effects but does not prevent regular flare ups and disease progression in >50% of patients necessitating step-up medication. The first step in this program is to look at safety, tolerability and preliminary efficacy of BGP014 in the approved Phase I multi-centre study with mild to moderate UC patients that will take place in Sweden.

The second program BGP345A looks to treat constipation in patients receiving opioid therapy for prescribed pain treatment. Opioids are an essential option for chronic pain, primarily back pain, rheumatism or post-operative pain, where non-opioid multimodal drugs or physical therapy are not providing relief. Opioid use can lead to a number of side effects with Opioid-Induced Constipation (OIC) being the most common with a varying prevalence of 41-81%. Current first line therapy is the use of laxatives but at least 45% of patients are laxative refractory and continue to have motility issues. The approved study is a Phase II multi-centre study to assess the safety and preliminary efficacy of BGP345A and will take place in France.

### **About BioGaia Pharma AB**

BGP is a subsidiary to BioGaia AB set up in 2017 to select and develop live microbial based pharmaceutical product candidates to address real medical needs. Candidates are selected based on supporting pre-clinical and clinical research. It has two prioritised programs.  
[www.biogaiaapharma.com](http://www.biogaiaapharma.com)

### **About BioGaia AB**

BioGaia is a Swedish world-leading probiotic company that has been at the forefront of microbiome research for more than 30 years. BioGaia develops, markets and sells probiotic products with documented health benefits. To date, over 200 articles on clinical trials with BioGaia's probiotic strains have been published. The products are sold by nutrition and pharmaceutical companies in more than 100 countries. The class B share of the Parent Company BioGaia AB is quoted on the Mid Cap segment of Nasdaq Stockholm.  
[www.biogaia.com](http://www.biogaia.com)

### **More information on the studies are available here:**

BGP014 - UC study

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2019-004578-25/SE>

BGP345A - OIC study

<https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-000239-29/FR>

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