



## **Naturally Splendid Announces Update on Health Canada Approved COVID-19 Clinical Trial and Strategic Outlook for Development of Cavaltinib™**

**Vancouver, British Columbia, April 1, 2021 - Naturally Splendid Enterprises Ltd.** ("Naturally Splendid", "NSE" or "the Company") (FRANKFURT: 50N) (TSX-V: NSP) (OTC: NSPDF) provides an update on the Health Canada approved, COVID-19 phase 2 clinical trial and strategic outlook for Plasm Pharmaceutical and development of the target drug Cavaltinib™.

We are pleased to announce that we are through the final planning and preparatory steps for the clinical trial designed to evaluate Cavaltinib™ pharmacology as a treatment for the COVID-19 disease pathology and are moving to select subjects for the Health Canada approved phase 2 clinical trial.

The clinical trial will be run through Plasm Pharmaceutical, a Joint Venture with Biologic Pharmamedical and Naturally Splendid. The Company is excited to have Cavaltinib™ recognized by Health Canada as a drug candidate for the treatment of COVID-19 patients. Cavaltinib™ is the result of over 15 years of research and development that has led to published medical findings and patented technology. The objective will be to establish the clinical evidence for Cavaltinib™ as a treatment option for high-risk patients to avoid hospitalization, morbidity and/or mortality upon SARS-CoV-2 infection.

In particular, the technology that forms the foundation to Cavaltinib™ has already been shown to inhibit the transcription of cytokines that are known to partake centrally in the COVID-related cytokine storm phenomenon. It is generally accepted that the cytokine storm phenomenon contributes to the COVID-19 pathology in a significant way exacerbating symptoms, risk of morbidity and demand for medical attention and hospitalization.

The current range of COVID-19 vaccines have been produced in an atypically short period of time and are thankfully beginning to have a positive effect. However, despite the vaccine successes, infection rates and cases of morbidity are still on the rise in many regions demonstrating the pandemic is not yet over. Reports indicate the health risk, due in large part to the escalation of variants, is still considered a high alert problem.

Treatment options such as Cavaltinib™ will be required as the SARS-CoV-2 coronavirus evolves through its inevitable mutations. It is anticipated throughout the medical community that the SARS-CoV-2 coronavirus and the pandemic may only be signs of what is to come as the environment that spawns these types of viruses continues to evolve due in part to rapid population growth and food supply logistics.

In earlier news releases the Company confirmed it has secured laboratory space, adequate supplies of Cavaltinib™ to conduct the 30-day phase 2 clinical trial, as well as secured significant manufacturing capacity in both Canada and the United States in anticipation of a positive outcome of the phase 2 clinical trial.

### **A Statement from the World Health Organization – March 30, 2021**

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World Health Organization Director-General Tedros Adhanom Ghebreyesus and leaders including Prime Minister Boris Johnson of Britain, Premier Mario Draghi of Italy and President Paul Kagame of Rwanda proposed "a renewed collective commitment" to reinforce preparedness and response systems by leveraging the UN health agency's constitution.

Speaking at a briefing Tuesday, Tedros said the time to act is now. "*The world cannot afford to wait until the pandemic is over to start planning for the next one.*"

President of the European Council Charles Michel, who also spoke on Tuesday, said that it's not a question of if the world will see another pandemic, but when. "COVID-19 has been a harsh reminder — no one is safe until everyone is safe," Michel said, noting that leaders need to take responsibility to ensure that pandemic preparedness and global health systems are fit for the 21st century.

### **A Statement from the Chief Public Health Officer of Canada – March 29, 2021**

While COVID-19 continues to impact people of all ages in Canada, infection rates are highest among those aged 20 to 39 years of age. Although severe illness is less common among young adults, it is important to remember that serious illness can occur at any age and evidence indicates that the B.1.1.7 variant of concern is associated with more severe illness outcomes in adults. In addition, circulation of COVID-19 in younger, more mobile and socially-connected adults presents an ongoing risk for spread into high-risk populations and settings. The emergence and spread of certain SARS-CoV-2 virus variants heightens this concern. For the week of March 14 to 20, there were on average of 101,165 tests completed daily across Canada, of which 3.7% were positive for COVID-19. As of March 28, a total of 8,266 variant of concern cases have been reported across Canada, including 7,725 involving B.1.1.7 variants, 272 P.1 variants and 269 B.1.351 variants.

### **Strategic Development for Cavaltinib™**

With the onset of COVID-19 and the understanding of the cytokine storm phenomenon as it relates to the disease pathology of the autoimmune conditions that were being studied by Biologic Pharmamedical Research prior to COVID, it became evident that Cavaltinib™ had the potential to play a significant role as a treatment for COVID patients.

This was the impetus for Health Canada to fast-track drug status of Cavaltinib™ to the phase 2 clinical trial stage to meet the needs of those infected with the COVID-19 virus.

*"We have come a long way from the original research initiative that honed in on the anti-inflammatory pharmacology of the drug in the context of disease pathologies associated with Ulcerative Colitis and other autoimmune-related diseases such as Crohn's, Rheumatoid Arthritis and Lupus."* says Franco Cavaleri, lead scientist and Plasm Pharmaceutical CEO. *"Our first victory round was in achieving approval for anti-*

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*inflammatory claims by Health Canada for this novel technology with the intention of engaging in clinical research to demonstrate indication-specific applications to treat these diseases. The opportunity to run a COVID-based phase 2 clinical trial with Cavaltinib™, will accelerate the development of this drug for other potential applications as noted”.*

Concurrently, this clinical trial sets the stage for expedition of Cavaltinib™ for clinical research and approved use for other indications. The pivot to focus on COVID-19 from the initial research is a logical one in the context of the bigger picture and the immediate need to find treatments for COVID. Research will continue in the area of auto-immune and anti-inflammatory indications after the clinical studies for COVID are completed.

As Cavaltinib™ gains drug status for the COVID-19 indication, it serves as a window of opportunity to fast-track the repurposing of the new drug for off-label applications. For the original indications of the Cavaltinib™ technology, we have seen strong preliminary promise for: ulcerative colitis, Crohn’s disease, asthma, COPD, arthritis and other autoimmune and autoinflammatory conditions.

Naturally Splendid CEO Mr. Craig Goodwin states, “*We have been working with Franco and Biologic Pharmamedical Research for over two years and are confident that the patented technology that is the foundation to Cavaltinib™ has great potential as a treatment for COVID as well as additional applications for other respiratory and auto-immune conditions. Our initial focus is for a COVID treatment. However, we believe the results from this clinical study will also provide valuable data on the effectiveness of Cavaltinib™ in other applications”.*

We caution that this news release is not making any express or implied claims that we have the ability to eliminate the COVID-19 virus at this time. The scientific content of this news release has been reviewed and approved by Biologic.

### **About Naturally Splendid Enterprises Ltd.**

Founded in 2010, NSE operates a Safe Quality Food Level 2 certified food manufacturing facility just outside Vancouver, BC in Canada. The Company has established numerous healthy, functional foods under recognized brands such as Natera Sport™, Natera Hemp Foods, CHII, Elevate Me™ and Woods Wild Bar™, and most recently Natera Plant Based Foods, a line of delicious plant-based meat alternatives for the rapidly growing plant-based market segment.

The Company has a myriad of new products and line extensions under development that are approaching launch. NSE, through its joint venture Plasm Pharmaceutical, has been approved for conducting a phase 2 clinical trial approved by Health Canada for treatment of COVID-19.

NSE has also developed proprietary technologies for the extraction of high-demand, healthy omega 3 and 6 oils from hemp.

NSE contract manufacturers for healthy, functional food products and ingredients focusing on plant-based ingredients. The Company provides contract manufacturing services for many healthy

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food companies, private labeling a wide variety of nutritional food products destined for global healthy food markets.

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On Behalf of the Board of Directors

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### **Forward-Looking Statements**

Information set forth in this news release contains forward-looking statements that are based on assumptions as of the date of this news release. These statements reflect management's current estimates, beliefs, intentions and expectations. They are not guarantees of future performance. Naturally Splendid cautions that all forward looking statements are inherently uncertain and that actual performance may be affected by a number of material factors, many of which are beyond Naturally Splendid's control including, Naturally Splendid's ability to compete with large food and beverage companies; sales of any potential products developed will be profitable; sales of shelled hemp seed will continue at existing rates or increase; the ability to complete the sales of all bulk hemp seed purchase orders; and the risk that any of the potential applications may not receive all required regulatory or legal approval. Accordingly, actual and future events, conditions and results may differ materially from the estimates, beliefs, intentions and expectations expressed or implied in the forward-looking information. Except as required under applicable securities legislation, Naturally Splendid undertakes no obligation to publicly update or revise forward-looking information.

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