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Dear members of the PWS community,

We at Soleno Therapeutics would like to provide an update on the status of DCCR.

As we have worked with the PWS community over the last several years, whether it is with advocacy leaders from PWSA USA and FPWR, or with leading clinical investigators, we have also had the opportunity to meet many individuals with PWS and their families. We have been struck by the scale of the unmet medical needs of the community, the resilience of the patients and the dedication of their families to find new treatments.

As you may know, to make a drug commercially available to patients in the US, a company must submit a New Drug Application, or NDA, to the FDA for review. This review period generally takes 6 to 10 months, during which the FDA evaluates all data to ensure that any drug they approve is safe and effective, and that the benefits outweigh the risks. To collect these data for an NDA, we ran a clinical trial – DESTINY PWS – and some of you may have children who participated in it.

We announced the results of DESTINY PWS in June of last year. The primary goal of the study was to evaluate whether DCCR treated patients showed a statistically significant improvement in hyperphagia compared to those treated with placebo. Unfortunately, the study did not meet this goal. However, the data did provide other evidence of efficacy while showing that most common side effects with DCCR (such as effects on glucose, edema and hypertrichosis) were as expected and, typically, manageable.

As you all know, PWS affects many body systems. Although there are similarities, the disease can be very different from individual to individual. We believe that it is important, in this rare disease setting, to consider both the evidence obtained from the study as well as from individual patient experiences. We also feel it is important to include analyses that account for the impact of the COVID-19 pandemic. It is this totality of evidence that we believe provides information on the potential risks and benefits of DCCR in PWS.

Prior to submitting an NDA, the typical process involves first discussing with the FDA the data from clinical studies to support submission. We have provided the overall topline DESTINY PWS analysis as well as our analyses accounting for the impact of the COVID-19 pandemic to the FDA. We do not have any agreement with the FDA on the submission of an NDA, and most recently the FDA informed us that a new clinical trial will be required. We are continuing our dialog with the FDA around the existing study data.

Recently, through PWSA USA and FPWR, many of you shared the experiences you had during the DESTINY PWS study and continue to have in Study C602, the extension study. This information was compiled and sent to FDA by the organizations last week. We believe that

individual patient experiences and the voice of the community are important and ask that you continue to work through these organizations to ensure that the FDA hears a single, united voice.

I know that one of your immediate concerns is for those who are on DCCR in C602. At this time, we have no immediate plans to stop the study and we will continue to provide DCCR to all active subjects in the study. Our goal remains to obtain regulatory approval for DCCR to make DCCR available commercially, which is the most effective way to provide broad access to this community. To achieve this goal, we need to ensure that there is a reasonable and clear path forward with the FDA, which we continue to be committed to. We will continue to provide public updates, but please know that these interactions with FDA take time and generally occur on a 3- to 4-month timeframe.

Thank you again for your continuing efforts to find new treatments and for your interest in DCCR and particularly to all those whose loved ones participated in the DESTINY PWS. You motivate and inspire us every day.

Anish Bhatnagar, MD
CEO
On behalf of all of us at Soleno