An Update to the Prader-Willi community from Harmony Biosciences:

As you may know, the team at Harmony has been working toward initiating a Phase 2 clinical trial to assess the safety, efficacy and appropriate dosing of pitolisant in treating some of the symptoms experienced by patients with Prader-Willi syndrome. We have an ongoing dialogue with the Foundation for Prader-Willi Research and the Prader-Willi Syndrome Association (USA), with the goal of collaborating to educate the PWS community about our upcoming clinical trial and recruitment efforts. I want to assure you that Harmony remains committed to the PWS community and continues to move forward with the work needed to start our Phase 2 clinical trial.

However, due to the importance of physical distancing and the current strain on healthcare resources during the COVID-19 pandemic, we cannot begin enrollment in the trial until the impact of this pandemic begins to subside, to ensure the trial can be completed under the rigors required by the protocol, including completing inpatient study procedures at the investigative sites. Based on the importance and nature of these procedures for this particular trial, there are no alternatives or contingency plans that we can put in place that would allow us to start the trial as we had hoped. We believe that during this period of uncertainty and strain on healthcare resources, we must all act responsibly and allow healthcare workers to focus on the current crisis.

At Harmony, patients are at the heart of everything we do. While we are currently physically distant, we want the PWS community to know we stand with you and are fully committed to our clinical efforts. Our priority continues to be to lead with the science and communicate about our progress. In the coming months, we look forward to sharing more information about when enrollment in our trial will begin.

Thank you for your patience as, together, we move forward during this unprecedented time. Please stay safe and be well.

Sincerely,

Jeffrey M. Dayno, MD
Executive Vice President & Chief Medical Officer, Harmony Biosciences, LLC