

**Data Presented at National Medical Association's Annual Convention and Scientific Assembly Evaluates the Burden of Severe RSV Disease among High-Risk Preterm Infants (29-35 wGA)**

On August 3<sup>rd</sup>, at the National Medical Association (NMA) 113<sup>th</sup> Annual Convention and Scientific Assembly in Detroit, AstraZeneca presented the initial results of SENTINEL1, an ongoing observational study of respiratory syncytial virus-confirmed hospitalizations (RSVHs) among US infants born at 29-35 weeks gestational age (wGA) not receiving immunoprophylaxis (IP).<sup>1</sup> The goal of the SENTINEL1 study is to assess the burden of severe RSV disease among preterm infants 29-35 wGA, following recent guidance that recommends against the use of IP for these infants.<sup>1</sup> Initial results are based on data of all eligible infants with an RSVH, irrespective of enrollment status.

The poster presentation included initial study results of data collected from 43 US hospitals, and represents one of the largest studies of preterm infants hospitalized with severe RSV disease to date.<sup>1</sup> In total, 709 infants with RSV-confirmed hospitalizations were observed among eligible 29-35 wGA infants; 243 infants were 29-32 wGA, 279 infants were 33-34 wGA, and 187 infants were 35 wGA.<sup>1</sup>

While previous clinical studies have shown that preterm infants born at  $\leq 35$  wGA have increased incidence of hospitalization and morbidity due to severe RSV disease, the SENTINEL1 initial results continue to support that RSV illness can be severe, frequently resulting in ICU admission and the need for mechanical ventilation (MV).<sup>1,2,3,4,5,6,7</sup>

Additionally, SENTINEL1 initial results demonstrate that RSV-confirmed hospitalizations, ICU admissions, and need for MV increased with younger chronological age.<sup>1</sup> Infants under 6 months of age accounted for the majority of RSVHs (78%), ICU admissions (87%), and the need for MV (92%).<sup>1</sup> Similar to previous RSV hospitalization studies, SENTINEL1 initial results demonstrated that RSV disease severity is greater in infants born at earlier gestational ages.<sup>8,9,10,11,12</sup>

Study investigators noted that these data further establish the real and significant risk of severe RSV disease in preterm infants born at 29-35 wGA, particularly within the first six months of life.<sup>1</sup> As such, in the absence of a vaccine to protect against severe RSV disease, these preterm infants remain at high risk for severe RSV disease.<sup>1</sup>

Additional analyses of results from the 2014-2015 RSV season are underway, and the study will also be continued through the 2015-2016 RSV season to collect additional data.

**References:**

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