Imcivree® (setmelanotide) – Expanded indication

- On December 20, 2024, Rhythm Pharmaceuticals announced the FDA approval of Imcivree (setmelanotide), to reduce excess body weight and maintain weight reduction long term in adults and **pediatric patients aged 2 years and older with syndromic or monogenic obesity due to**: (1) Bardet-Biedl syndrome (BBS) and (2) pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.
    - Imcivree was previously approved for this indication in patients aged 6 years and older.
- BBS and POMC, PCSK1 and LEPR deficiencies are rare melanocortin-4 receptor pathway diseases characterized by impaired satiety, abnormal food-seeking behaviors, and early-onset obesity.
- The approval of Imcivree for the expanded indication was based on a study in 12 pediatric patients aged 2 to less than 6 years with obesity due to POMC, PCSK1, or LEPR deficiency or BBS. Imcivree dose titration occurred over an 8-week period, followed by a 44-week open-label treatment period with Imcivree.
    - The mean percent change in body mass index (BMI) after 52 weeks of Imcivree treatment was -33.8%, -13.1%, and -9.7% in patients with POMC deficiency, LEPR deficiency, and BBS, respectively.
- The recommended starting dosage of Imcivree is 0.5 mg (0.05 mL) injected subcutaneously once daily for 2 weeks in pediatric patients aged 2 to less than 6 years.
- Refer to the Imcivree drug label for titration instructions and dosing in patients 6 years and older.