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Singapore: Novartis has recieved USFDA approval for Promacta (eltrombopag) for the treatment of children six years and older with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

Promacta was approved by the FDA in 2008 for use in adult patients with the same condition.

ITP is characterized by a low platelet count and upto 30 percent of affected children experience persistent disease for more than six months and are diagnosed with chronic ITP.

"Young patients with chronic ITP who have either an insufficient response to or side effects from standard therapies have limited treatment options, making this FDA approval of eltrombopag for children six years and older particularly important," said Dr James B Bussel, professor, Weill Cornell Medical College, and lead study investigator of the PETIT study. "Through the eltrombopag studies, one of which is the largest randomized trial ever performed in children with chronic ITP, we discovered that Promacta - a treatment that can be taken once daily by mouth and shown to be well tolerated - can manage this disorder and help these young patients."

"Today's FDA approval of Promacta for children with chronic ITP, a rare and potentially serious blood disorder, gives new hope to patients and their families," said Mr Bruno Strigini, president, Novartis Oncology. "All patients are important, but when

we can help children, we are especially gratified. This approval underscores our expertise in benign hematologic disease and our commitment to provide treatments for rare diseases."