

DISEASE BURDEN



Breast cancer is the most common cancer in women and the second most common cancer worldwide. In 2022, there were over 2.29 million new cases of breast cancer in women. About two-thirds of breast cancers in women aged 50 years or younger are HR positive and HER2 negative.



CLINICAL RELEVANCE



The addition of ribociclib to endocrine therapy, the usual initial treatment, resulted in significantly longer overall survival than endocrine therapy alone. About 70% of people in the ribociclib group were still alive after 42 months, while only 46% were alive in the placebo group.



SERVICE DELIVERY ENABLERS

Diagnosis of breast cancer is provided in the public health sector in many LMICs, but a high proportion of cases is only detected at an advanced/metastatic stage of the disease. Generic companion treatments are usually available.





Novartis

REGULATORY

INTELLECTUAL PROPERTY LANDSCAPE



Ribociclib is approved by stringent regulatory authorities. Potential sublicensees of ribociclib could rely on mechanisms like USFDA Para III, Swissmedic MAGHP or EU-M4all for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.



MANUFACTURING

The product requires a standard manufacturing process for tablets. There are no anticipated challenges in relation to excipients or final packaging. Due to a probable occupational exposure band (OEB) category 4, a special facility might be required. Shelf life is three years at room temperature.

MARKET



Ribociclib is available in several LMICs, primarily in the private sector, but