Press Release No 18 11 April 2025

AIFA Board of Directors approves the reimbursability of 2 medicines

Iqirvo (elafibranor), an orphan drug for the treatment of patients with primary biliary cholangitis (CBP), will be reimbursed.

At its extraordinary meeting on 10 April 2025, the Board of Directors of the Italian Medicines Agency decided that an orphan medicine and a new chemical molecule should be eligible for reimbursement by the National Health Service (NHS).

The orphan medicine that the NHS will reimburse is **Iqirvo** (indicated for the treatment of **primary biliary cholangitis (CBP)**, a rare and progressive liver disease that can lead to liver failure, need for liver transplantation and death. It is an autoimmune disease that predominantly affects women between 45 and 65 years of age, with a prevalence in Italy estimated at around 28 cases per 100,000 inhabitants.
Iqirvo is indicated in combination with ursodesoxycholic acid (AUDC) in adults who show an inadequate response to AUDC, or as monotherapy in adults who cannot tolerate AUDC.

The new chemical entity that will be eligible for reimbursement is **Orserdu (elacestrant)**, indicated as monotherapy for the treatment of postmenopausal women and men with locally advanced or metastatic breast cancer.

The medicines authorised and admitted for reimbursement by the NHS are indicated below, along with their therapeutic indications:

NEW MEDICINES AND EXTENSION OF INDICATIONS BoD 10 APRIL 2025*

TIPOLOGIA NEGOZIAZIONE	PRINCIPIO ATTIVO	FARMACO	INDICAZIONI TERAPEUTICHE
Farmaci orfani per malattie rare	Elafibranor	IQIRVO	Iqirvo è indicato per il trattamento della colangite biliare primitiva (primary biliary cholangitis, PBC) in associazione con acido ursodesossicolico (ursodeoxycholic acid, UDCA) in soggetti adulti che mostrano una risposta inadeguata all'UDCA oppure in monoterapia in soggetti adulti che non sono in grado di tollerare l'UDCA.
Nuove entità chimiche	Elacestrant	ORSERDU	ORSERDU in monoterapia è indicato per il trattamento di donne in postmenopausa, e di uomini, con carcinoma mammario localmente avanzato o metastatico positivo per i recettori degli estrogeni (ER) e negativo per HER2, con una mutazione attivante di ESR1, che mostrano progressione della malattia in seguito ad almeno una linea di terapia endocrina comprendente un inibitore di CDK 4/6.

* N.B. For further information (class and supply regime, innovativeness, register, procedure number), please see the annex to this press release.