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AIFA Board of Directors of 17 July 2024

Five new medicines approved, including two anti-cancer drugs

President Nisticò: "A backlog of hundreds of files cleared in three months"

Five new medicines were approved by the AIFA Board of Directors on 17 July on the recommendation of the CSE, the Scientific and Economic Commission for Medicines: an anti-leukaemic, a medicine against alopecia, one against ulcerative colitis, a medicine against advanced melanoma, and an anti-allergy drug. A total of 43 dossiers have been examined and approved, including Tecvayli in monotherapy, which is moving from class C of non-reimbursable products to class H(OSP) of products paid for by the State and which is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three previous therapies.

'AIFA's commitment to making new therapies accessible to citizens as quickly as possible continues,' says the Agency's President, Robert Nisticò. *'With these latest deliberations, we can say that in just three months the new CSE and the Board of Directors have cleared a backlog of hundreds of dossiers, accumulated during the transition phase from the old to the new AIFA. The goal for the future',* he concludes*, 'is now to drastically reduce the time for the authorisation of new medicines, so as to align the speed of research as much as possible with the usability of pharmaceutical innovation for citizens'.*

In detail, the new medicines approved are:

- Inaqovi (decitabine and cedazuridine), indicated as monotherapy for the treatment of adult patients with newly diagnosed acute myeloid leukaemia unsuitable for standard induction chemotherapy;
- Litfulo (Ritlecitinib), indicated in severe alopecia areata in adults and adolescents aged 12 years and older;

- Omvoh (Mirikizumab), indicated for the treatment of adult patients with moderate to severe active ulcerative colitis who have had an inadequate response, have lost response, or are intolerant to conventional therapy or biologic treatment;
- Opdualag (Nivolumab/Relatlimab), indicated for the first-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents aged 12 years or older;
- the allergen extract Palforzia, for the treatment of patients aged 4-17 years with a confirmed diagnosis of peanut allergy;

All newly approved medicines have been classified as Class H products for hospital use.

A total saving of 19 million euros is estimated as a result of the approval of 11 generic medicines. An estimated saving of 54 million euros results from the approval of the equivalent version, with a 40% price reduction, of a major immunosuppressant (pomalidomide).

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