Supplementary material

Risk assessment in atopic dermatitis: guidance from a multidisciplinary expert panel

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M.I.R.A. PROJECT

July to December 2023

RATIONALE

In January 2023, EMA's Human Medicines Committee endorsed the measures recommended by the Pharmacovigilance Risk Assessment Committee to minimise the risk of serious adverse effects (i.e., major adverse cardiovascular (MACE), venous thromboembolism (VTE), cancer and serious infections) in patients with chronic inflammatory disorders treated with Janus kinase inhibitors (JAKi). EMA recommends that JAK inhibitors should be used only if no other suitable treatment alternatives are available in patients aged ≥ 65 years, individuals at increased risk of major cardiovascular problems (such as heart attack or stroke), individuals who smoke or have done so for a long time in the past, persons at increased risk of cancer, and in those with risk factors for VTE. Moreover, if possible, the JAKi dosing should be reduced in these patient groups. EMA updated the product information for JAKi used to treat chronic inflammatory disorders accordingly.

The **M**ultiple **I**n-treatment **R**isk **A**ssessment & Management (M.I.R.A.) project was conceived by AbbView to identify the needs of specialists in dermatology who treat patients with atopic dermatitis (one of the indications for upadacitinib) regarding the assessment of risk factors listed in upadacitinib's Summary of Product Characteristics.

OBJECTIVES

The specific M.I.R.A. project objectives included:

1. Conceiving a shared approach in the clinical evaluation of the patient with atopic dermatitis (AD) to be treated with upadacitinib
2. Creating an environment for multidisciplinary discussion with various specialists involved in the assessment of the individual risk (cardiologist, haematologist, oncologist and pulmonologist) to encourage scientific exchange
3. Drafting a Clinical Assessment Form, a structured tool to facilitate risk assessment by a dermatologist.

PROJECT DESCRIPTION

The M.I.R.A. project was developed in three stages:

1. During the **first virtual meeting** (July 18th, 2023), a multidisciplinary scientific board met to establish the best working method including the formation of four three-person working groups. Each group was composed of two dermatologists and a specialist in the specific clinical area linked to the risk factors (cardiologist for risk of MACE, haematology for DVE, and oncologist for cancer, pulmonology to better quantify the risk of cancer related to smoking).
   An ad hoc cloud-based platform was created to support the work of all physicians involved.
2. The **working groups** met virtually in September to identify the needs of the dermatologists and discuss the risk assessment in the area of expertise of the non-dermatologist and devise a Clinical Assessment form.
3. During the **final in person meeting** in Rome (December 5th, 2023), the working groups shared with the others the results of their work.

Supplementary Figure 1. Patient profile form.