EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Assessment report

Onureg

International non-proprietary name: azacitidine

Procedure No. EMEA/H/C/004761/0000

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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List of abbreviations

Abbreviation or Specialist Term	Explanation
ADR	Adverse drug reaction
AE	Adverse event
AESI	Adverse event of special interest
ALT	Alanine aminotransferase
AML	Acute myeloid leukemia
ANC	Absolute neutrophil count
AST	Aspartate aminotransferase
AUC	Area under the curve
AUCss	Area under the concentration curve at steady state
BMI	Body mass index
BSC	Best supportive care
CCR	Conventional care regimens
CHMP	Committee for Human Medicinal Products
CI	Confidence interval
Clcr	Creatinine clearance
Cmax	Maximum concentration
Cmax,ss	Peak plasma concentration at steady state
CMML	Chronic myelomonocytic leukemia
CR	Complete remission
CRF	Case report form
CRi	Complete remission with incomplete blood count recovery
CSR	Clinical study report
CYP	Cytochrome P450
DFS	Disease-free survival
DNA	Deoxyribonucleic acid
DS	Differentiation syndrome
ECOG	Eastern Cooperative Oncology Group
EEA	European Economic Area
EFS	Event-free survival
ELN	European LeukemiaNet
EMA	European Medicines Agency
EP	Eosinophilic pneumonia
EQ-5D-3L	European Quality of Life-Five Dimensions-Three Levels
ER	Exposure-response
EU	European Union
EU-27	European Union of 27 member states
FAB	French-American-British (classification system)
FACIT-F	Functional Assessment of Chronic Illness Therapy – Fatigue
FDA	Food and Drug Administration
FLT3	fms-like tyrosine kinase 3
G-CSF	Granulocyte colony-stimulating factor
GCP	Good Clinical Practice
GO	Gemtuzumab ozogamicin
HDC	Histamine dihydrochloride
HMA	Hypomethylating agent
HR	Hazard ratio
HRQoL	Health-related Quality-of-Life
HSCT	Hematopoietic stem cell transplantation
ICF	Intended commercial formulation
ICH	International Council for Harmonisation
IDH	Isocitrate dehydrogenase

IPSS	International Prognostic Scoring System
ISS	Integrated Summary of Safety
ITD	Internal tandem duplication
ITT	Intent-to-treat
IV	Intravenous
IVRS	Interactive Voice Response System
IWG	International Working Group
KIR	Killer-cell immunoglobulin-like receptor
LDAC	Low dose-cytarabine
LFS	Leukemia-free survival
MA	Marketing authorisation
MDS	Myelodysplastic syndromes
MedDRA	Medical Dictionary for Regulatory Affairs
MID	Minimally important difference
mITT	Modified intent-to-treat
MM	Multiple myeloma
MRD	Minimal residual disease
NCCN	National Comprehensive Cancer Network
NDA	New Drug Application
OS	Overall survival
PD	Pharmacodynamic
PK	Pharmacokinetics
PML	Progressive multifocal leukoencephalopathy
PT	Preferred term
QD	Once daily
RA	Refractory anaemia
RAEB	Refractory anaemia with excess blasts
RAEB-T	Refractory anaemia with excess blasts in transformation
RARS	Refractory anaemia with ringed sideroblasts
RBC	Red blood cell
RFS	Relapse-free survival
RNA	Ribonucleic acid
SAP	Statistical Analysis Plan
SBP	Summary of Biopharmaceutical Studies
SC	Subcutaneous
SCE	Summary of Clinical Efficacy
SCP	Summary of Clinical Pharmacology
SCS	Summary of Clinical Safety
SMQ	Standard MedDRA query
SOC	System organ class
SPA	Special Protocol Assessment
TEAE	Treatment-emergent adverse event
UK	United Kingdom
US	United States
WBC	White blood cell
WHO	World Health Organization

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