Approval at EMA 2015

EMA **APPROVED A TOTAL OF 41 NASs IN 2015** WITH A MEDIAN APPROVAL TIME OF **417 DAYS***

THE MEDIAN EU COMMISSION TIME WAS 60 DAYS, THE AGENCY TIME 242 DAYS AND COMPANY TIME 110 DAYS

Type of Medicine

15 BIOLOGIC NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF **408 DAYS**

26 CHEMICAL NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF **428 DAYS**

13 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF **428 DAYS**

28 NASs IN OTHER THERAPY AREAS APPROVED IN 2015 WITH A MEDIAN APPROVAL TIME OF **417 DAYS**

Designation and Review Type

8 EXPEDITED NAS APPROVALS IN 2015** WITH A MEDIAN APPROVAL TIME OF **282 DAYS,** THIS IS A MEDIAN **164 DAYS FASTER** THAN THE **33 STANDARD NAS APPROVALS IN 2015**

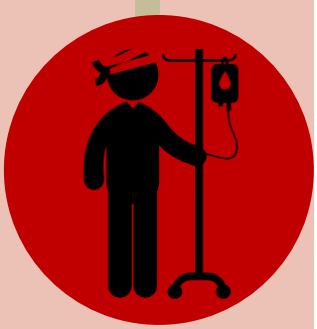
15 ORPHAN NAS APPROVALS IN 2015 WITH A MEDIAN APPROVAL TIME OF **453 DAYS,** THIS IS A MEDIAN **37 DAYS SLOWER** THAN THE **26 NON-ORPHAN NAS APPROVALS IN 2015**

Availability in EMA

24% OF THE NASs APPROVED IN 2015 BY EMA WERE APPROVED BY EMA **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT FDA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA**

76% OF THE NASs APPROVED IN 2015 BY EMA WERE APPROVED AT FDA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA **FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED IN EMA**

THE MEDIAN **SUBMISSION GAP*** ** TO EMA FOR THESE NASs WAS **60 DAYS**



*The EMA approval time includes the EU Commission time.

**'Expedited review' refers to EMA 'Accelerated Assessment and FDA/PMDA/Health Canada/Swissmedic 'Priority Review'.

***Date of submission at the first regulatory agency to the date of regulatory submission to the target agency .