Approval at FDA 2017

FDA *(CDER AND CBER)* **APPROVED A TOTAL OF 50 NASs IN 2017,** WITH A MEDIAN APPROVAL TIME OF **243 DAYS**

Type of Medicine

16 BIOLOGIC NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF **241 DAYS**

34 CHEMICAL NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF **244 DAYS**

19 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF **214 DAYS**

31 NASs IN OTHER THERAPY AREAS APPROVED IN 2017, WITH A MEDIAN APPROVAL TIME OF **293 DAYS**

Designation and Review Type

31 EXPEDITED NAS APPROVALS IN 2017, WITH A MEDIAN APPROVAL TIME OF **240 DAYS;** THIS IS A MEDIAN **125 DAYS FASTER** THAN THE **19 STANDARD NAS APPROVALS IN 2017**

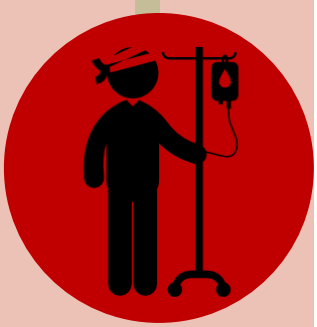
21 ORPHAN NAS APPROVALS IN 2017, WITH A MEDIAN APPROVAL TIME OF **242 DAYS;** THIS IS A MEDIAN **92 DAYS FASTER** THAN THE **29 NON-ORPHAN NAS APPROVALS IN 2017**

Availability in FDA

86% OF THE NASs APPROVED IN 2017 BY FDA WERE APPROVED BY FDA **FIRST OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL AT EMA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA**

14% OF THE NASs APPROVED IN 2017 BY FDA WERE APPROVED AT EMA, PMDA, HEALTH CANADA, SWISSMEDIC OR TGA **FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED IN FDA**

THE MEDIAN **SUBMISSION GAP** TO FDA FOR THESE NASs WAS **175 DAYS**



'Expedited review' refers to EMA 'Accelerated Assessment and FDA/PMDA/Health Canada/Swissmedic 'Priority Review'.
Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.