PCN37
September 12-14, 2019

NEW FDA-APPROVED DRUGS FOR BREAST, COLORECTAL, PROSTATE AND LUNG CANCER, AND BRAZILIAN HORIZON SCANNING OPPORTUNITY

TATIANE BOMFIM RIBEIRO[1], ADALTON GUIMARÃES RIBEIRO[2], MOACYR R. CUCE NOBRE[1 3]

[1]Departamento de Medicina Preventiva, Faculdade de Medicina da Universidade de São Paulo - Brazil, [2]Secretaria Estadual de Saúde - São Paulo - Brazil, [3]Instituto do Coração (InCor) do Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo - Brazil

Cancer caused 9.5million deaths in 2018

The most common cancer types diagnosed worldwide are lung, breast, colorectal, and prostate cancer.

The global expenditure on anticancer drugs and supportive care exceeded US$ 130 billion

FDA Is the 1st to new drug approval (70%)

FDA assessment for **Horizon Scanning** in Latin America

to identify and monitor new and emerging health technologies

OBJECTIVE

This study aimed to analyze the new molecular entity (NME) approved by FDA for lung, breast, prostate, and colorectal cancer from 2016 to 2018. Brazilian National Health Surveillance Agency (ANVISA) registration was assessed in order to provide Horizon Scanning (HS) candidates.

METHODS

Data were collected on the FDA online database, Drugs@FDA, for NME approved. Approval date, generic name, biomarker, and FDA special designation for shorter approval were assessed. Regarding those NME, ANVISA registry was checked on February 18th, 2019.

RESULTS

EIGHT NEW MOLECULAR ENTITY APPROVED BY THE FDA

Four (50%) for breast cancer, three (37.5%) for lung cancer, one (12.5%) for prostate, and none for colorectal.

87.5% used an FDA special designation to fasten review

87.5% used a biomarker (i.e., HER-2, HR, ALK, gBRCAm, EGFR)

Ribociclib and apalutamide; the differences on approval time between FDA and ANVISA were respectively 16 and 9 months.

Horizon Scanning ANVISA: talazoparib, abemaciclib, neratinib, lorlatinib, dacomitinib and brigatinib

CONCLUSION

Biomarker and fast review pathway accounted for 87.5% of the FDA approvals. Six drugs can be used for potential HS in Brazil.

tatianeribeiro@usp.br