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Registres des Cancers général de la Manche, général du Calvados, digestif du Calvados et des hémopathies malignes de Basse-Normandie

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Estimate of the number of Italian cancer patients eligible for immune checkpoint inhibitors

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This cross-sectional study was aimed at estimating the number of Italian incident cancer patients in 2020 eligible for immune checkpoint inhibitors (ICI). ICI are immunotherapy drugs effective for some metastatic/advanced tumours. The study is based on publicly available data: the ICIs approved until August 2022 by the Italian Medicines Agency (AIFA) with their specific indications, cancer incidence estimates at 2020 (Italian network of cancer registries – AIRTUM) and observed cancer deaths (proxy for metastasis), and published papers with estimates on the frequency of different cancer stage/histology/markers etc. corresponding to AIFA authorisations. In the analysed period a total of 7 ICIs (ipilimumab, nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab) were authorized in Italy for 20 cancer types (see Table). The estimated number of ICI-eligible patients in 2020 was 48,365, 14.4% of those tumours that may fit AIFA-indications, and 10.5% of all the malignant incident tumours, including skin epitheliomas. The indications that most contributed to the eligibility estimate were NSCLC (25.4%), hepatocellular carcinoma (15.8%) and SCLC (10.0%). Within single cancer the highest proportions of patients eligible to ICI therapy were for oesophagus (56.6% squamous cell and 10.8% adenocarcinoma), hepatocellular carcinoma (58.7%), mesothelioma (49,0%), and lung (30.1% NSCLC and 11.8% SCL), and 26.7% for stomach (adenocarcinoma).

Cancer registries should exploit their data to enrich the debate on new drugs which includes enthusiasms for the expected results but also doubts about their toxicity their effective real-world benefit and the sustainability of their costs, providing to oncologists, policy makers, and any other stakeholder the quantification of the theoretical target population.

Cancer	Overall incident	ICI Eligible	Total	95% CI	Site	95% CI
	n.	n.	%		%	
Head&Neck (squamous)	9856	2652	5.5	5.3-5.7	26.9	26.0-2.8
Oesophagus (squamous)	2394	1356	2.8	2.7-3.0	56.6	54.6-58.6
Oesophagus (ADK/HER2-/PD-L1 CPS>=5)		258	0.5	0.5-0.6	10.8	9.6-12.1
Stomach (ADK/HER2-/PD-L1 CPS>=5)	14556	3883	8.0	7.8-8.3	26.7	26.0-27.4
Stomach (dMMr or MSI-H)		534	1.1	1.0-1.2	3.7	3.4-4.0
Colorectal (dMMr or MSI-H)	43702	2835	5.9	5.7-6.0	6.5	6.3-6.7
Small intestine 9.4-11.9	699	17	0.03	0.02-0.06	2.4	1.4-3.9
Hepatocellular carcinoma	13012	7642	15.8	15.5-16.1	58.7	57.9-59.5
Bladder (dMMr or MSI-H)	5400	296	0.6	0.5-0.7	5.5	4.9-6.1
Lung cancer (NSCLC)	40882	12300	25.4	25.0-25.8	30.1	29.6-30.5
Lung cancer (SCLC)		4824	10.0	9.7-10.2	11.8	11.5-12.1
Mesothelioma	1986	973	2.0	1.9-2.1	49.0	46.8-51.2
Melanoma (stage IIB-IV)	14863	2751	5.7	5.5-5.9	18.5	17.9-19.1
Squamous epithelioma	19000	380	0.8	0.7-0.9	2.0	1.8-2.2
Basal cell epithelioma	64000	320	0.7	0.6-0.7	0.5	0.4-0.6
Merkel cell carcinoma	228	16	0.03	0.01-0.05	7.0	4.1-11.1
Female breast (TN)	54976	333	0.7	0.6-0.7	0.6	0.5-0.7
Cervical (PD-L1 cps>=1)	2365	267	0.6	0.5-0.6	11.3	10.0-12.6
Endometrial (dMMr or MSI-H)	8335	743	1.5	1.4-1.6	8.9	8.3-9.5
Urothelial* (PD-L1>=5%)	25492	2572	5.3	5.1-5.5	10.1	9.7-10.5
Kidney (Renal cell)	13521	3191	6.6	6.4-6.8	23.6	22.9-24.3
Hodgkin lymphoma	2151	224	0.5	0.4-0.5	10.4	9.2-11.8
All	335,267	48365	100.0		14.4	14.3-14.5

ICI:immune checkpoint inhibitors; ADK: adenocarcinoma; dMMR:mismatch repair deficient ; MSI-H: microsatellite instability; NSCLC: non small cell lung cancer; SCLC small cell lung cancer; TN triple negative; PD-L1: Programmed death-ligand 1 ; CPS: combined positive score