Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 355 – 2 April 2021)

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
1.	Adcetris 50mg, powder for concentrate for solution for infusion [Brentuximab Vedotin 50mg]	**INDICATION :** Adcetris is indicated for the treatment of adult patients with previously untreated sALCL or other CD30-expressing Peripheral T-Cell Lymphoma (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin and prednisone. **POSOLOGY:** Previously untreated sALCL or other CD30-expressing PTCL The recommended dose in combination with chemotherapy (cyclophosphamide[C], doxorubicin[H] and prednisone[P] [CHP] is 1.8 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks for 6 to 8 cycles. (see section CLINICAL STUDIES). Primary prophylaxis with growth factor support (G-CSF), beginning with the first dose is recommended for all patients with previously untreated sALCL or other CD30-expressing PTCL receiving combination therapy (see section Warnings and Precautions). Refer to the product information of chemotherapy agents given in combination with Adcetris for treatment of patients with previously untreated sALCL or other CD30-expressing PTCL.	**TAKEDA MALAYSIA SDN. BHD.** Unit TB-L 13-1, Level 13, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Marketing Authorization Holder</th></tr>
<tr><td>2.</td><td>Lynparza 100 mg Film-Coated Tablets [Olaparib 100mg]

Lynparza 150 mg Film-Coated Tablets [Olaparib 150mg]</td><td>
INDICATION :

<u>Pancreatic cancer</u>
Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

POSOLOGY:
Table 1 Biomarker Testing for Patient Selection
<table>
<tr><th rowspan="2">Indication</th><th rowspan="2">Biomarker</th><th colspan="2">Sample Type</th></tr>
<tr><th>Tumour</th><th>Blood</th></tr>
<tr><td>First-line maintenance treatment of BRCA-mutated advanced ovarian cancer*</td><td>BRCA1m, BRCA2m</td><td>X</td><td>X</td></tr>
<tr><td>Maintenance treatment of platinum-sensitive relapsed ovarian cancer</td><td>No requirement for biomarker testing</td><td></td><td></td></tr>
<tr><td>gBRCA1/2-mutated HER2-negative metastatic breast cancer</td><td>gBRCA1m, gBRCA2m</td><td></td><td>X</td></tr>
<tr><td>First-line maintenance treatment of germline BRCA-mutated metastatic pancreatic adenocarcinoma</td><td>gBRCA1m, gBRCA2m</td><td></td><td>X</td></tr>
</table>
* Where testing fails or tissue sample is unavailable/insufficient, or when germline testing is negative, consider using an alternative test.
First-line maintenance treatment of germline BRCA-mutated metastatic pancreatic adenocarcinoma:
It is recommended that treatment be continued until disease progression or unacceptable toxicity.
</td><td>ASTRAZENECA SDN. BHD.
Level 11 & 12,
Nucleus Tower,
No. 10, Jalan PJU 7/6,
Mutiara Damansara,
47800 Petaling Jaya,
Selangor.</td></tr>
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<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Marketing Authorization Holder</th></tr>
<tr><td>3.</td><td>Invokana 100mg Film-Coated Tablets [Canaglifozin 100mg]

Invokana 300mg Film-Coated Tablets [Canaglifozin 300mg]</td><td>
INDICATION :

Patients with Diabetic Nephropathy
As an adjunct to diet, exercise, and standard of care therapy to reduce the risk of end-stage kidney disease, doubling of serum creatinine, and cardiovascular (CV) death in adult patients with type 2 diabetes mellitus and diabetic nephropathy with albuminuria (> 33.9 mg/mmol).

POSOLOGY :
Renal impairment
For treatment of diabetic kidney disease as add on to standard of care (eg. ACE-inhibitors or ARBs), a dose of 100 mg canagliflozin once daily should be used (see table 1). Because the glycaemic lowering efficacy of canagliflozin is reduced in patients with moderate renal impairment and likely absent in patients with severe renal impairment, if further glycaemic control is needed, the addition of other anti-hyperglycaemic agents should be considered. For dose adjustments, recommendations according to eGFR refer to Table 1.

Table 1: Dose adjustment recommendations[a]
<table>
<tr><th>eGFR (mL/min/1.73 m^2) or CrCl (mL/min)</th><th>Total daily dose of canagliflozin</th></tr>
<tr><td>≥ 60</td><td>Initiate with 100 mg.

In patients tolerating 100 mg and requiring additional glycaemic control, the dose can be increased to 300 mg.</td></tr>
<tr><td>45 to < 60[a]</td><td>Initiate with 100 mg.

Continue 100 mg for patients already taking Invokana.</td></tr>
<tr><td>30 to < 45[a,b]</td><td>Initiate with 100 mg.

Continue 100 mg for patients already taking Invokana.</td></tr>
</table>
</td><td>JOHNSON & JOHNSON SDN BHD
Lot 3 & 5,
Jalan Tandang,
46050 Petaling Jaya,
Selangor.</td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
		< 30[a,b] — Continue 100 mg for patients already taking Invokana.[c] Invokana should not be initiated. [a] If further glycaemic control is needed, the addition of other anti hyperglycaemic agents should be considered [b] With albuminuria (>33.9 mg/mmol) [c] Continue dosing until dialysis or renal transplant	