Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 384, 11 Mei 2023

Products approved for additional indication (DCA 384 – 11 May 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Olumiant 2mg Film-Coated Tablets [Baricitinib 2mg] Olumiant 4mg Film-Coated Tablets [Baricitinib 4mg]	**INDICATION :** Alopecia areata Baricitinib is indicated for the treatment of severe alopecia areata in adult patients. **POSOLOGY :** Alopecia areata The recommended dose of baricitinib is 4 mg once daily. A dose of 2 mg once daily may be appropriate for patients such as those aged ≥ 75 years and for patients with a history of chronic or recurrent infections. A dose of 2 mg once daily may also be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering. Once a stable response has been achieved, it is recommended to continue treatment for at least several months, in order to avoid relapse. The benefit-risk of treatment should be re-assessed at regular intervals on an individual basis. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 36 weeks of treatment.	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Xeljanz Film-Coated Tablets 5mg [Tofacitinib Citrate (equivalent to tofacitinib 5mg)]	**INDICATION :** <u>Ulcerative Colitis</u> XELJANZ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have an inadequate response or who are intolerant to TNF blockers. Limitations of Use: Use of XELJANZ in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **POSOLOGY :** **Recommended Dosage in <u>Ulcerative Colitis</u>** Table 2 displays the recommended adult daily dosage of XELJANZ and dosage adjustments for patients receiving CYP2C19 and/or CYP3A4 inhibitors, with moderate or severe renal impairment (including but not limited to those with severe insufficiency who are undergoing hemodialysis) or moderate hepatic impairment, with lymphopenia, neutropenia or anemia). **Table 2: Recommended Dosage of XELJANZ in Patients with UC**	**PFIZER (MALAYSIA) SDN. BHD.** Level 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

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No.	Product [Active Ingredient]	Additional Indication		Product Registration Holder (PRH)
			XELJANZ	
		Adult patients	**Induction:** 10 mg twice daily for at least 8 weeks, evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed, continue 10 mg twice daily for a maximum of 16 weeks. Discontinue 10 mg twice daily after 16 weeks if adequate therapeutic response is not achieved. **Maintenance:** 5 mg twice daily. For patients with loss of response during maintenance treatment, a dosage of 10 mg twice daily may be considered and limited to the shortest duration, with careful consideration of the benefits and risks for the individual patient. Use the lowest effective dose needed to maintain response.	
		Patients receiving: • strong CYP3A4 inhibitors (e.g., ketoconazole), or • a moderate CYP3A4 inhibitor(s) with a strong CYP2C19 inhibitor(s) (e.g., fluconazole)	If taking 10 mg twice daily, reduce to 5 mg twice daily. If taking 5 mg twice daily, reduce to 5 mg once daily.	

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<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>Patients with:
moderate or severe renal impairment
moderate hepatic impairment*</td><td>If taking 10 mg twice daily, reduce to 5 mg twice daily.
If taking 5 mg twice daily, reduce to 5 mg once daily.
For patients undergoing hemodialysis, dose should be administered after the dialysis session on dialysis days. If a dose was taken before the dialysis procedure, supplemental doses are not recommended in patients after dialysis.</td></tr>
<tr><td>Patients with lymphocyte count less than 500 cells/ mm^3, confirmed by repeat testing</td><td>Discontinue dosing.</td></tr>
<tr><td>Patients with ANC 500 to 1000 cells/ mm^3</td><td>If taking 10 mg twice daily, reduce to 5 mg twice daily. When ANC is greater than 1000, increase to 10 mg twice daily based on clinical response.
If taking 5 mg twice daily, interrupt dosing. When ANC is greater than 1000, resume 5 mg twice daily.</td></tr>
<tr><td>Patients with ANC less than 500 cells/ mm^3</td><td>Discontinue dosing.</td></tr>
<tr><td>Patients with hemoglobin less than 8 g/ dL or a decrease of more than 2 g/ dL</td><td>Interrupt dosing until hemoglobin values have normalized.</td></tr>
</table>
*Use of XELJANZ in patients with severe hepatic impairment is not recommended.
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	VALDOXAN 25MG FILM-COATED TABLETS [Agomelatine 25mg]	**INDICATION :** Valdoxan is indicated for the treatment of generalised anxiety disorder (GAD). **POSOLOGY :** The recommended dose is 25 mg once daily taken orally at bedtime. If there is no improvement of symptoms, the dose may be increased to 50 mg once daily, i.e. two 25 mg tablets, taken together at bedtime: • 2 weeks after treatment initiation in major depressive disorder. • 4 weeks after treatment initiation in generalised anxiety disorder. Elderly The efficacy and safety of agomelatine (25 to 50mg/day) have been established in elderly depressed patients (< 75years). No dose adjustment is required in relation to age. No effect is documented in depressed patients ≥75 years nor in elderly patients suffering from generalised anxiety disorder. Therefore, agomelatine should not be used by patients in this age group.	**SERVIER MALAYSIA SDN. BHD.** Unit No. 25-02, Level 25, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 384 – 11 May 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	CABOMETYX 20mg film-coated tablets [Cabozantinib (S)-malate 20mg] CABOMETYX 40mg film-coated tablets [Cabozantinib (S)-malate 40mg] CABOMETYX 60mg film-coated tablets [Cabozantinib (S)-malate 60mg]	**INDICATION :** Differentiated thyroid carcinoma (DTC) CABOMETYX is indicated as monotherapy for the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC), refractory or not eligible to radioactive iodine (RAI) who have progressed during or after prior systemic therapy. **POSOLOGY :** Therapy with CABOMETYX should be initiated by a physician experienced in the administration of anticancer medicinal products. Posology CABOMETYX tablets and cabozantinib capsules are not bioequivalent and should not be used interchangeably (see section 5.2). CABOMETYX as monotherapy For RCC, HCC and DTC, the recommended dose of CABOMETYX is 60 mg once daily. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs.	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	Kryxana 200mg Film-coated Tablets [Ribociclib succinate 254.40mg (equivalent to 200mg of ribociclib free base)]	**INDICATION :** KRYXANA is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with: ● an aromatase inhibitor as initial endocrine-based therapy in pre/perimenopausal or postmenopausal women or in men; or ● fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men. **POSOLOGY :** Pre/perimenopausal women, or men treated with the combination KRYXANA plus an aromatase inhibitor should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards. Men treated with the combination of KRYXANA plus fulvestrant should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 384 – 11 May 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
6.	BRILINTA 90MG FILM-COATED TABLET [Ticagrelor 90 mg]	**INDICATION :** Acute Ischemic Stroke or Transient Ischemic Attack (TIA) BRILINTA is indicated to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale score ≤5) or high-risk transient ischemic attack (TIA). **POSOLOGY :** Acute Ischemic Stroke or Transient Ischemic Attack (TIA) Initiate treatment with a 180 mg loading dose of Brilinta and then continue with 90 mg twice daily for up to 30 days. The treatment effect accrued early in the course of therapy. Use Brilinta with a loading (300 to 325 mg) and a daily maintenance dose of ASA of 75 to 100 mg.	**ASTRAZENECA SDN. BHD.** Level 11 & 12, The Bousteador, No. 10, Jalan PJU 7/6, Mutiara Damansara, 47800 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 384 – 11 May 2023)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
7.	Repatha Solution for Injection in Pre-filled Syringe 140mg/mL (evolocumab) Repatha Solution for Injection in Pre-filled Autoinjector 140mg/mL (evolocumab) [Evolocumab 140 mg/ml]	**INDICATION :** <u>Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)</u> REPATHA is indicated for the reduction of elevated low-density lipoprotein cholesterol (LDL-C) in adult patients with primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]): • as an adjunct to diet and statin therapy, with or without other lipid-lowering therapies, in patients who require additional lowering of LDL-C, • as an adjunct to diet, alone or in combination with non-statin lipid-lowering therapies, in patients for whom a statin is contraindicated. **REPATHA is indicated as an adjunct to diet and other LDL-C-lowering therapies (e.g., statins, ezetimibe) in pediatric patients aged 10 years and older with HeFH who require additional lowering of LDL-C.** <u>Homozygous Familial Hypercholesterolemia</u> REPATHA is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) **in adults and pediatric patients aged 10 years and older** with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C. **POSOLOGY :** The recommended subcutaneous dosage of REPATHA in adults with established cardiovascular disease or in adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) is either 140 mg every 2 weeks OR 420 mg once monthly, based on patient preference for dosing frequency and injection volume. When switching dosage regimens, administer the first dose of the new regimen on the next	**AMGEN BIOPHARMACEUTICALS MALAYSIA SDN. BHD.** Suite 9.01, Level 9, Menara Summit, Persiaran Kewajipan USJ 1, UEP, 47600 Subang Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		scheduled date of the prior regimen. **In pediatric patients aged 10 years and older with HeFH:** - **The recommended dosage of REPATHA is either 140 mg every 2 weeks OR 420 mg once monthly administered subcutaneously.** - **If switching dosage regimens, administer the first dose of the new regimen on the next scheduled date of the prior regimen.** The recommended subcutaneous dosage of REPATHA **in adult and pediatric patients aged 10 years and older** with HoFH is 420 mg once monthly. In patients with HoFH, measure LDL-C levels 4 to 8 weeks after starting REPATHA, since response to therapy will depend on the degree of LDL-receptor function.	