Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 409, 22 Mei 2025

Products approved for additional indication (DCA 409 – 22 May 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	TS-ONE OD Tablet 20 [Tegafur 20 mg, Gimeracil 5.8 mg and Oteracil potassium 19.6 mg] TS-ONE OD Tablet 25 [Tegafur 25 mg, Gimeracil 7.25 mg and Oteracil potassium 24.5 mg]	**INDICATION :** TS-ONE® is indicated in adults • For the postoperative adjuvant chemotherapy for hormone receptor (HR)-positive and human epidermal growth factor 2 (HER2)-negative breast cancer at high risk of recurrence. **POSOLOGY :** For postoperative adjuvant chemotherapy for HR-positive and HER2-negative breast cancer at high risk of recurrence Note 1) The standard initial recommended dose for TS-ONE® is based on the patient's BSA as per Table 1. TS-ONE® should be taken after meals twice daily, morning and evening, for 14 consecutive days followed by a 7-day rest, in combination with endocrine therapy. This treatment cycle is repeated every 3 weeks. This is regarded as one course of the regimen and is continued for up to 1 year. The dose can be decreased or increased according to the patient's condition. The dose should not be increased more than the patient's initial dose. **Note 1) High risk of recurrence was defined as patients with the following (1) or (2) in the Phase III Clinical Study (POTENT study) protocol.** (1) Patients with axillary lymph node metastasis (positive axillary lymph node metastasis before drug therapy in patients undergoing preoperative or postoperative drug therapy). (2) Patients who are negative for axillary lymph node metastasis and meet any of the following 1) to 3). 1) No history of preoperative drug therapy: (i) invasion diameter of 3 cm or more, (ii) histological grade (HG) 3, (iii) evident vascular invasion, (iv) HG2 with an invasion diameter of 2 cm or more and less than 3 cm, (v) HG2, an invasion diameter of less than 2 cm and high proliferation markers*, or (vi) HG1, an invasion diameter of 2 cm or more and less than 3 cm and high proliferation markers*. 2) A history of preoperative chemotherapy: Residual invasive cancer is observed in the	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

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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>
surgical specimen of the primary tumour or axillary lymph node.
3) History of preoperative endocrine therapy: (i) invasion diameter of 3 cm or more, (ii) HG3, (iii) evident vascular invasion, (iv) HG2 and invasion diameter of 2 cm or more in the surgical specimen <3 cm, (v) HG2, invasion diameter <2 cm and high proliferation marker*, or (vi) HG1, invasion diameter ≥2 cm and <3 cm and high proliferation marker*.
*: Ki-67 labelling index ≥30% or if Ki-67 labelling index was ≥14% and <30% by central pathological assessment, Oncotype DX measurement will be performed, and patients with recurrence score (RS) ≥18 will be eligible.

If the creatinine clearance (CrCl) is 50 ml/min or greater and less than 80 ml/min, start the treatment cycle with the following dosage.

Table 2: TS-ONE® starting dose for postoperative adjuvant chemotherapy for HR-positiv and HER2-negative breast cancer patients at high risk of recurrence, according creatinine clearance values at the start of the cycle of treatment

<table>
<tr><th>Creatinine clearance (CrCl)*</th><th>Body surface area</th><th>Initial dose (tegafur equivalent)</th></tr>
<tr><td rowspan="3">≥ 50 ml/min,
< 80 ml/min</td><td>< 1.25 m^2</td><td>20 mg in the morning
40 mg in the evening</td></tr>
<tr><td>≥ 1.25 m^2, < 1.5 m^2</td><td>40 mg each time</td></tr>
<tr><td>≥ 1.5 m^2</td><td>50 mg each time</td></tr>
</table>
* If there is no measured CrCl value using 24-hour pooled urine, an estimate will be calculated using the Cockcroft-Gault formula.
Cockcroft-Gault equation
CrCl estimate = ((140 - Age) x Weight (kg)) / (72 x Serum creatinine (mg/dL)) (For women, further, multiply the obtained value by 0.85)
Efficacy and safety in patients with CrCl less than 50 ml/min have not yet been established.
</td><td></td></tr>
</table>

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Products approved for additional indication (DCA 409 – 22 May 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Xtandi 40mg Soft Capsules [Enzalutamide 40 mg]	**INDICATION :** Xtandi is indicated: • as monotherapy or in combination with androgen deprivation therapy for the treatment of adult men with high-risk biochemical recurrent (BCR) non-metastatic hormone-sensitive prostate cancer (nmHSPC) who are unsuitable for salvage-radiotherapy **POSOLOGY :** Posology Medical castration with a luteinising hormone-releasing hormone (LHRH) analogue should be continued during treatment of patients with CRPC or mHSPC who are not surgically castrated. Patients with high-risk BCR nmHSPC may be treated with Xtandi with or without a LHRH analogue. For patients who receive Xtandi with or without a LHRH analogue, treatment can be suspended if PSA is undetectable (< 0.2 ng/mL) after 36 weeks of therapy. Treatment should be reinitiated when PSA has increased to ≥ 2.0 ng/mL for patients who had prior radical prostatectomy or ≥ 5.0 ng/mL for patients who had prior primary radiation therapy. If PSA is detectable (≥ 0.2 ng/mL) after 36 weeks of therapy, treatment should continue. Paediatric population There is no relevant use of enzalutamide in the paediatric population in the indication of treatment of patients with CRPC, mHSPC, or high-risk BCR nmHSPC.	**ASTELLAS PHARMA MALAYSIA SDN BHD** Unit 9.02 And 9.03, Level 9, Corporate Tower 2, Pavilion Damansara Heights 3, Jalan Damanlela, Pusat Bandar Damansara, 50490 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.

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Products approved for additional indication (DCA 409 – 22 May 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Lonsurf Film-coated Tablet 20 mg/8.19 mg (Trifluridine/ Tipiracil) [Trifluridine 20 mg/ Tipiracil Hydrochloride 9.420 mg (equivalent to 8.19 mg of Tipiracil)] Lonsurf Film-coated Tablet 15 mg/6.14 mg (Trifluridine/ Tipiracil) [Trifluridine 15 mg/ Tipiracil Hydrochloride 7.065 mg (equivalent to 6.14 mg of Tipiracil)]	**INDICATION :** Metastatic Colorectal Cancer • Lonsurf®, as a single agent or in combination with bevacizumab, is indicated for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy. **POSOLOGY :** **DOSAGE AND ADMINISTRATION** Lonsurf® should be prescribed by physicians experienced in the administration of anti-cancer therapy. Recommended Dose The recommended starting dose of Lonsurf® in adults, as a single agent or in combination with bevacizumab, is 35 mg/m^2/dose administered orally twice daily within one hour of completion of morning and evening meals on Days 1 to 5 and Days 8 to 12 of each 28-day cycle until disease progression or unacceptable toxicity. When Lonsurf® is used in combination with bevacizumab for the treatment of metastatic CRC, the dose of bevacizumab is 5 mg/kg of body weight given once every 2 weeks. Please refer to the full product information for bevacizumab. The dosage is calculated according to body surface area (BSA) (see Table 1). The dosage must not exceed 80 mg/dose. If doses were missed or held, the patient must not make up for missed doses.	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor.

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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 1: Starting dose calculation according to body surface area (BSA)
<table>
<tr><th rowspan="2">Starting dose</th><th rowspan="2">BSA (m^2)</th><th rowspan="2">Dose in mg (2x daily)</th><th colspan="2">Tablets per dose (2x daily)</th><th rowspan="2">Total daily dose (mg)</th></tr>
<tr><th>15 mg/6.14 mg</th><th>20 mg/8.19 mg</th></tr>
<tr><td rowspan="10">35 mg/m^2</td><td>< 1.07</td><td>35</td><td>1</td><td>1</td><td>70</td></tr>
<tr><td>1.07 - 1.22</td><td>40</td><td>0</td><td>2</td><td>80</td></tr>
<tr><td>1.23 - 1.37</td><td>45</td><td>3</td><td>0</td><td>90</td></tr>
<tr><td>1.38 - 1.52</td><td>50</td><td>2</td><td>1</td><td>100</td></tr>
<tr><td>1.53 - 1.68</td><td>55</td><td>1</td><td>2</td><td>110</td></tr>
<tr><td>1.69 - 1.83</td><td>60</td><td>0</td><td>3</td><td>120</td></tr>
<tr><td>1.84 - 1.98</td><td>65</td><td>3</td><td>1</td><td>130</td></tr>
<tr><td>1.99 - 2.14</td><td>70</td><td>2</td><td>2</td><td>140</td></tr>
<tr><td>2.15 - 2.29</td><td>75</td><td>1</td><td>3</td><td>150</td></tr>
<tr><td>≥ 2.30</td><td>80</td><td>0</td><td>4</td><td>160</td></tr>
</table>

Dose Modifications for Adverse Reactions

Dosing adjustments may be required based on individual safety and tolerability. A maximum of 3 dose reductions are permitted to a minimum dose of 20 mg/m2 twice daily. Dose escalation is not permitted after it has been reduced.

In the event of hematological and/or non-hematological toxicities, patients should follow the dose interruption, resumption and reduction criteria stated in Table 2, Table 3 and Table 4.
</td><td></td></tr>
</table>

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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 2: Dose interruption and resumption criteria for hematological toxicities related to myelosuppression
<table>
<tr><th>Parameter</th><th>Interruption criteria</th><th>Resumption criteria[a]</th></tr>
<tr><td>Neutrophils</td><td>< 0.5 ´ 10^9/L</td><td>³ 1.5 ´ 10^9/L</td></tr>
<tr><td>Platelets</td><td>< 50 ´ 10^9/L</td><td>³ 75 ´ 10^9/L</td></tr>
</table>
[a] Resumption criteria applied to the start of the next cycle for all patients regardless of whether or not the interruption criteria were met.

Table 3: Recommended dose modifications for Lonsurf® in case of hematological and non-hematological adverse reactions
<table>
<tr><th>Adverse reaction</th><th>Recommended dose modifications</th></tr>
<tr><td>• Febrile neutropenia
• CTCAE* Grade 4 neutropenia (< 0.5 ´ 10^9/L) or thrombocytopenia (< 25 ´ 10^9/L) that results in more than 1 week’s delay in start of next cycle
• CTCAE* non-hematologic Grade 3 or Grade 4 adverse reaction; except for Grade 3 nausea and/or vomiting controlled by anti-emetic therapy or diarrhea responsive to anti-diarrheal medicinal products</td><td>• Interrupt dosing until toxicity resolves to Grade 1 or baseline.
• When resuming dosing, decrease the dose level by 5 mg/m^2/dose from the previous dose level (Table 4 or Table 5 in severe renal impairment).
• Dose reductions are permitted to a minimum dose of 20 mg/m^2/dose twice daily (or 15 mg/m^2/dose twice daily in severe renal impairment).
• Do not increase dose after it has been reduced.</td></tr>
</table>
* Common terminology criteria for adverse events
</td><td></td></tr>
</table>

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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 4: Dose reductions according to body surface area (BSA)
<table>
<tr><th rowspan="2">Reduced dose</th><th rowspan="2">BSA (m^2)</th><th rowspan="2">Dose in mg (2x daily)</th><th colspan="2">Tablets per dose (2x daily)</th><th rowspan="2">Total daily dose (mg)</th></tr>
<tr><th>15 mg/6.14 mg</th><th>20 mg/8.19 mg</th></tr>
<tr><td colspan="6">Level 1 dose reduction: From 35 mg/ m^2 to 30 mg/ m^2</td></tr>
<tr><td rowspan="7">30 mg/m^2</td><td>< 1.09</td><td>30</td><td>2</td><td>0</td><td>60</td></tr>
<tr><td>1.09 - 1.24</td><td>35</td><td>1</td><td>1</td><td>70</td></tr>
<tr><td>1.25 - 1.39</td><td>40</td><td>0</td><td>2</td><td>80</td></tr>
<tr><td>1.40 - 1.54</td><td>45</td><td>3</td><td>0</td><td>90</td></tr>
<tr><td>1.55 - 1.69</td><td>50</td><td>2</td><td>1</td><td>100</td></tr>
<tr><td>1.70 - 1.94</td><td>55</td><td>1</td><td>2</td><td>110</td></tr>
<tr><td>1.95 - 2.09</td><td>60</td><td>0</td><td>3</td><td>120</td></tr>
<tr><td>30 mg/m^2</td><td>2.10 - 2.28</td><td>65</td><td>3</td><td>1</td><td>130</td></tr>
<tr><td></td><td>≥ 2.29</td><td>70</td><td>2</td><td>2</td><td>140</td></tr>
<tr><td colspan="6">Level 2 dose reduction: From 30 mg/ m^2 to 25 mg/ m^2</td></tr>
</table></td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication						Product Registration Holder (PRH)
		25 mg/ m^2	< 1.10	25 [a]	2 [a]	1 [a]	50[a]	
			1.10 - 1.29	30	2	0	60	
			1.30 - 1.49	35	1	1	70	
			1.50 - 1.69	40	0	2	80	
			1.70 - 1.89	45	3	0	90	
			1.90 - 2.09	50	2	1	100	
			2.10 - 2.29	55	1	2	110	
			≥ 2.30	60	0	3	120	
		Level 3 dose reduction: From 25 mg/ m^2 to 20 mg/ m^2						
		20 mg/ m^2	< 1.14	20	0	1	40	
			1.14 - 1.34	25[a]	2 [a]	1 [a]	50[a]	
			1.35 - 1.59	30	2	0	60	
			1.60 - 1.94	35	1	1	70	

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	1.95 - 2.09	40	0	2	80
	2.10 - 2.34	45	3	0	90
	≥ 2.35	50	2	1	100

[a] At a total daily dose of 50 mg, patients should take 1 x 20 mg/8.19 mg tablet in the morning and 2 x 15 mg/6.14 mg tablets in the evening.

2.3 Recommended Dose for Renal Impairment

Mild or moderate renal impairment (creatinine clearance (CLcr) 30 to 89 mL/min)
No adjustment of the starting dose is recommended in patients with mild (CLcr 60 to 89 mL/min) or moderate renal impairment (CLcr 30 to 59 mL/min). [see Use in Specific Populations (7.7), Clinical Pharmacology (10.3)]

Severe renal impairment (CLcr 15 to 29 mL/min)

For patients with severe renal impairment, a starting dose of 20 mg/m^2 twice daily on Days 1 through 5 and Days 8 through 12 of each 28-day cycle is recommended. [see Use in Specific Populations (7.7), Clinical Pharmacology (10.3)]. One dose reduction to a minimum dose of 15 mg/m^2 twice daily is permitted based on individual safety and tolerability (see Table 5). Dose escalation is not permitted after it has been reduced.

In the event of hematological and/or non-hematological toxicities, patients should follow the dose interruption, resumption and reduction criteria stated in Table 2, Table 3 and Table 5.

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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 5: Starting dose and dose reduction in patients with severe renal impairment according to body surface area (BSA)
<table>
<tr><th rowspan="2">Reduced dose</th><th rowspan="2">BSA (m^2)</th><th rowspan="2">Dose in mg (2x daily)</th><th colspan="2">Tablets per dose (2x daily)</th><th rowspan="2">Total daily dose (mg)</th></tr>
<tr><th>15 mg/6.14 mg</th><th>20 mg/8.19 mg</th></tr>
<tr><td colspan="6">Starting dose</td></tr>
<tr><td rowspan="7">20 mg/m^2</td><td>< 1.14</td><td>20</td><td>0</td><td>1</td><td>40</td></tr>
<tr><td>1.14 - 1.34</td><td>25[a]</td><td>2[a]</td><td>1[a]</td><td>50[a]</td></tr>
<tr><td>1.35 - 1.59</td><td>30</td><td>2</td><td>0</td><td>60</td></tr>
<tr><td>1.60 - 1.94</td><td>35</td><td>1</td><td>1</td><td>70</td></tr>
<tr><td>1.95 - 2.09</td><td>40</td><td>0</td><td>2</td><td>80</td></tr>
<tr><td>2.10 - 2.34</td><td>45</td><td>3</td><td>0</td><td>90</td></tr>
<tr><td>≥ 2.35</td><td>50</td><td>2</td><td>1</td><td>100</td></tr>
<tr><td colspan="6">Dose reduction: From 20 mg/m^2 to 15 mg/m^2</td></tr>
<tr><td rowspan="2">15 mg/m^2</td><td>< 1.15</td><td>15</td><td>1</td><td>0</td><td>30</td></tr>
<tr><td>1.15 - 1.49</td><td>20</td><td>0</td><td>1</td><td>40</td></tr>
<tr><td rowspan="4">15 mg/m^2</td><td>1.50 - 1.84</td><td>25[a]</td><td>2[a]</td><td>1[a]</td><td>50[a]</td></tr>
<tr><td>1.85 - 2.09</td><td>30</td><td>2</td><td>0</td><td>60</td></tr>
<tr><td>2.10 - 2.34</td><td>35</td><td>1</td><td>1</td><td>70</td></tr>
<tr><td>≥ 2.35</td><td>40</td><td>0</td><td>2</td><td>80</td></tr>
</table></td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		[a] At a total daily dose of 50 mg, patients should take 1 x 20 mg/8.19 mg tablet in the morning and 2 x 15 mg/6.14 mg tablets in the evening. <u>End stage renal disease (CLcr below 15 mL/min or requiring dialysis)</u> Administration is not recommended in patients with end stage renal disease as there are no data available for these patients. [see Use in Specific Populations (7.7), Clinical Pharmacology (10.3)] **2.4 Method of Administration** Lonsurf® is for oral use. The tablets must be taken with a glass of water within 1 hour after completion of the morning and evening meals.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
4.	Arexvy Powder and suspension for suspension for injection [Respiratory syncytial virus PreFusion protein 3 (RSVPreF3) antigen 120 mcg]	**INDICATION :** Arexvy is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in: • adults 50 through 59 years of age who are at increased risk for RSV disease.	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** Hz.01, Horizon Penthouse, 1 Powerhouse, 1, Persiaran Bandar Utama, Bandar Utama, 47800 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 409 – 22 May 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
5.	AFSTYLA 250IU powder and solvent for solution for injection AFSTYLA 500IU powder and solvent for solution for injection AFSTYLA 1000IU powder and solvent for solution for injection AFSTYLA 2000IU powder and solvent for solution for injection AFSTYLA 3000IU powder and solvent for solution for injection. [Lonoctocog alfa]	**POSOLOGY :** <u>Previously untreated patients</u> Overall, the safety and efficacy profile of AFSTYLA in PUPs was consistent with the benefit-risk profile reported in the previously treated patients (PTPs) except for the occurrence of neutralizing antibodies, which is a recognized risk of FVIII replacement therapy in this patient's population.	**DKSH MALAYSIA SDN. BHD.** B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 409 – 22 May 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
6.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	**INDICATION :** KEYTRUDA, in combination with gemcitabine and cisplatin, is indicated for the first-line treatment of locally advanced unresectable or metastatic biliary tract carcinoma in adults.rothelial carcinoma	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 409 – 22 May 2025)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
7.	NOVOSEVEN 1MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION [Eptacog alfa (activated) (Recombinant coagulation factor VIIa) 1mg] NOVOSEVEN 2MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION [Eptacog alfa (activated) (Recombinant coagulation factor VIIa) 2mg]	**INDICATION :** 4.1 Therapeutic indications NovoSeven® is indicated for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in the following patient groups: • in patients with congenital haemophilia with inhibitors to coagulation factors VIII or IX > 5 Bethesda Units (BU) • in patients with congenital haemophilia who are expected to have a high anamnestic response to factor VIII or factor IX administration • in patients with acquired haemophilia • in patients with congenital FVII deficiency • in patients with Glanzmann's thrombasthenia with past or present refractoriness to platelet transfusions, or where platelets are not readily available Severe postpartum haemorrhage NovoSeven® is indicated for the treatment of severe postpartum haemorrhage when uterotonics are insufficient to achieve haemostasis.	**NOVO NORDISK PHARMA (MALAYSIA) SDN. BHD.** Menara 1 Sentrum, Level 16, No. 201, Jalan Tun Sambathan, 50470 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.