Retevmo - (40 mg and 80 mg ; Capsule)

Generic Name	Selpercatinib	**Innovator**	Eli Lilly
Dosage	40 mg and 80 mg ; Capsule	**Branded US Sales**	Less Than $1000 mn
Probable FTF	None	**Known Para IV Filers**	None
Other ANDA developers	Less Than 5	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	RETEVMO ® is a kinase inhibitor indicated for the treatment of: • Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test • Adult and pediatric patients 12 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy • Adult and pediatric patients 12 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate) • Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.		
Complexities	Yes		

Chronology Of Events

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Executive Summary

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Patent Status

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Launch Timelines and Competition

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Chronology Of Events

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Retevmo - (40MG, 80MG)

Generic Name	Selpercatinib	**Innovator**	None
Dosage	40MG, 80MG	**Branded US Sales**	Less Than $1000 mn
Probable FTF	None	**Known Para IV Filers**	None
Other ANDA developers	None	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	RETEVMO® is a kinase inhibitor indicated for the treatment of: • Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test. • Adult and pediatric patients 12 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy. • Adult and pediatric patients 12 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)1 • Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options . This indication is approved under accelerated approval based on overall respon		
Complexities	Yes		

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Retevmo - (120MG, 160MG, 40MG, 80MG)

Generic Name	Selpercatinib	**Innovator**	None
Dosage	120MG, 160MG, 40MG, 80MG	**Branded US Sales**	Less Than $1000 mn
Probable FTF	None	**Known Para IV Filers**	None
Other ANDA developers	None	**Tentative Approvals**	None
Final Approvals	None	**Generic Launches**	None
Indication	RETEVMO® is a kinase inhibitor indicated for the treatment of: • Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test. • Adult and pediatric patients 12 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test, who require systemic therapy. • Adult and pediatric patients 12 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate)1 • Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options . This indication is approved under accelerated approval based on overall respon		
Complexities	Yes		

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