



**fisher clinical**  
**services**

by Thermo Fisher Scientific

**CLPS LABEL PROOF**



**Label ID#:** LIL10962CS1

**Label Designed By:** Robert Weathers

**Label Revised By:** Robert Weathers

**Template ID#:** 5250.1750.DP+.1250cp.2250bk1.1875bk2

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**

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Loxo Oncology, Inc., 281 Tresser Boulevard, Stamford, CT 06901, USA, +1 855 569 6305 LIL10962	

**Label ID #: LIL10962PN1**

**Label Description: Cover Panel - Table of Contents (6pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

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**Label ID #: LIL10962PN2**

**Label Description: Inside Cover Panel - Table of Contents (Cont.) (6 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**

(i) Lote: AR  
 (ii) Fecha de caducidad:  
 (iii) Número de envases:  
 (iv) Número de confirmación:  
 (v) Fecha de fabricación:  
 (vi) Número de paciente:  
 Investigador: \_\_\_\_\_  
 Vitar: \_\_\_\_\_  
 100 mg LY3627727 (LOXO-305) pibotrubinb.  
 Cantidad de comprimidos: 62 por frasco.  
 Solamente para uso por vía oral. Tomar según las  
 indicaciones del investigador. Tagar los comprimidos  
 enteros. No triturar, romper ni masticar. Almacenar a  
 temperatura ambiente (de 10°C a 30°C). No destruir.  
 Devolver los envases y los medicamentos no usados al  
 investigador. Para uso exclusivo en ensayos clínicos.  
 © Mantener fuera del alcance de los niños.

**Label ID #: LIL10962PN3**

**Label Description: Argentina (Spanish) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**



Lot: \_\_\_\_\_  
 (i) Expiry Date: \_\_\_\_\_  
 (ii) Package Number: \_\_\_\_\_  
 (iii) Confirmation Number: \_\_\_\_\_  
 (iv) Manufacture Date: \_\_\_\_\_  
 Patent number: \_\_\_\_\_  
 Investigator: \_\_\_\_\_  
 100 mg LY352727 (LOXO-305) pibrotinib.  
 Tablet count: 62 per bottle. For oral use only.  
 Take as directed by investigator. Swallow tablets whole.  
 Do not crush, break or chew. Store at room temperature  
 (10°C - 30°C; 50°F - 86°F). Do not destroy. Return  
 packaging and unused medication to the investigator.  
 For clinical trial use only. Keep out of reach of children.  
 ELLI LILLY Australia Pty. Limited Level 9, 60 Margaret Street  
 Sydney NSW 2000 AUSTRALIA + 61 2 9325 4444 ④

Label ID #: LIL10962PN4

Label Description: Australia (English) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI:                     SIGNATURE ON FILE

(I) Ch.-B.:  
(II) Verwendbar bis:  
(III) Paket-Nr.:  
(IV) Bestätigungs-Nr.:  
(V) Herstellungsdatum:  
Patienten-Nr.:  
Pflanzl-Nr.:  
100 mg LY352727 (LOXO-305) Pimobutid.  
Anzahl Tabletten: 62 je Flasche. Zum Einnehmen.  
Nach Anweisung des Pflanzlers einnehmen, nicht öffnen.  
Tabletten unzerkaut oder zerkauen. Bei Raumtemperatur lagern  
(10°C - 30°C). Nicht vernichten. Verpackung und  
unverbräuchtes Arzneimittel dem Pflanzler zurückgeben.  
Zur klinischen Prüfung bestimmt.  
© Arzneimittel für Kinder unzugänglich aufbewahren.

AT

**Label ID #:** LIL10962PN5

**Label Description:** Austria (German) (5 pt.)

**Protocol #:** J2N-MC-JZNX

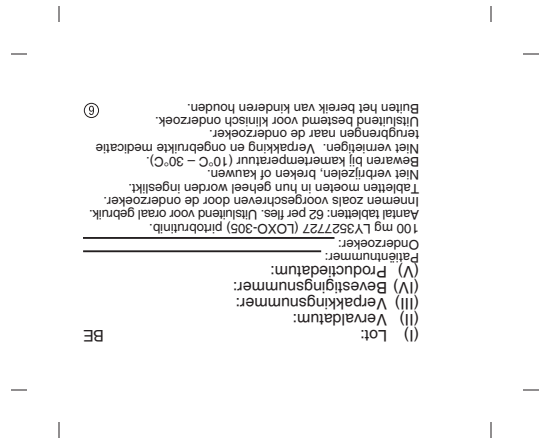
**Label Designed By:**

**Label Updated By:**

**Template ID #:** TCN12501

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***



**Label ID #:** LIL10962PN6

**Label Description:** Belgium (Dutch) (5 pt.)

**Protocol #:** J2N-MC-JZNX

**Label Designed By:**

**Label Updated By:**

**Template ID #:** TCN12501

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***

(I) Lot :  
(II) Date de péremption :  
(III) Numéro de kit :  
(IV) Numéro de confirmation :  
(V) Date de fabrication :  
Numéro du patient :  
Investigateur :  
100 mg LY362777 (LOXO-305) pibrotinib.  
Nombre de comprimés : 62 par flacon.  
Pour voie orale uniquement. À prendre conformément aux  
instructions de l'investigateur. Avoir les comprimés en  
entier. Ne pas les écraser, ni les casser, ni les mâcher.  
À conserver à température ambiante (entre 10°C et 30°C).  
Ne pas détruire. Retourner les emballages et les  
médicaments non utilisés à l'investigateur.  
Pour recherche biomédicale uniquement.  
⑦ Tenir hors de la portée des enfants.

Label ID #: LIL10962PN7

Label Description: Belgium (French) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:


Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: **SIGNATURE ON FILE** \_\_\_\_\_



(I) Ch.-B.:  
(II) Verwendbar bis:  
(III) Paket-Nr.:  
(IV) Bestätigungs-Nr.:  
(V) Herstellungsdatum:  
Pfalzen-Nr.:  
Pfalzen-Nr.:  
100 mg LY352727 (LOXO-305) Pirobutinib.  
Anzahl Tabletten: 62 je Flasche. Zum Einnehmen.  
Nach Anweisung des Pfärztes einnehmen, nicht öffnen.  
Tabletten unverkaut einnehmen, nicht öffnen.  
Bei Raumtemperatur lagern (10°C - 30°C).  
Nicht vernichten. Verpackung und unverbrauchtes  
Arzneimittel dem Pfärarzt zurückgeben.  
Zur klinischen Prüfung bestimmt.  
Arzneimittel für Kinder unzugänglich aufbewahren. 

Label ID #: LIL10962PN8

Label Description: Belgium (German) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: **SIGNATURE ON FILE** \_\_\_\_\_



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**LABEL PROOF**

(I) Lote: BR  
 (II) Data de validade:  
 (III) Número da embalagem:  
 (IV) Número da confirmação:  
 (V) Data de fabricação:  
 Número do paciente: \_\_\_\_\_  
 Investigador: \_\_\_\_\_  
 100 mg LY352727 (LOXO-305) LY352727.  
 Quantidade de comprimidos: 62 por frasco.  
 Apenas para uso oral. Tomar de acordo com as  
 instruções dadas pelo investigador. Engolir os comprimidos  
 inteiros. Não esmagar nem quebrar nem mastigar.  
 Armazenar à temperatura ambiente (10°C - 30°C).  
 Não destruir. Devolver a embalagem e os  
 medicamentos não utilizados ao investigador.  
 Para uso exclusivo em Pesquisa Clínica.  
 ③ Manter fora do alcance das crianças.

**Label ID #: LIL10962PN9**

**Label Description: Brazil (Portuguese) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***

(i) Lot: CA  
(ii) Expiry Date:  
(iii) Package Number:  
(iv) Confirmation Number:  
(v) Manufacture Date:  
Investigator:  
Patent number:  
100 mg LY352727 (LOXO-305) pirtobrutinib  
Tablet count: 62 per bottle. For oral use only.  
Take as directed by investigator. Swallow tablets whole.  
Do not crush, break or chew. Store at room temperature  
(10°C - 30°C; 50°F - 86°F). Do not destroy.  
Return packaging and unused medication to the  
Investigator. Investigational Drug: To Be Used By  
Qualified Investigator Only. Keep out of reach of children.  
Eli Lilly Canada Inc., Toronto, Canada  
MSX 181

Label ID #: LIL10962PN10

Label Description: Canada (English) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: \_\_\_\_\_ **SIGNATURE ON FILE**



(I) C. šarže:  
(II) Použitelné do:  
(III) Císlo balení:  
(IV) Ověřovací číslo:  
(V) Datum výroby:  
(VI) Císlo pacienta:  
Zkoušející lékař:  
100 mg LY352727 (LOXO-305) LY352727  
Počet tablet 62 v jedné lahvi. Pouze pro perorální podání.  
Užívejte podle pokynů zkušejícího. Pijte tablety  
ve skupu. Tablety neďte, nepřesahujte ani nezvyšujte.  
Uchovávejte při pokojové teplotě (10 °C - 30 °C).  
Nevyžaduje. Prázdná balení a nevyužitvané léky vafte  
zkoušejícímu. Pouze pro účely klinického hodnocení.  
Uchovávejte mimo dosah dětí.  
®

Label ID #: LIL10962PN12

Label Description: Czech Republic (Czech) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: \_\_\_\_\_ **SIGNATURE ON FILE**

(I) Lot: \_\_\_\_\_  
(II) Udløbsdato: \_\_\_\_\_  
(III) Pakningsnummer: \_\_\_\_\_  
(IV) Bækræftelsesnummer: \_\_\_\_\_  
(V) Følnummer: \_\_\_\_\_  
(VI) Følnummer: \_\_\_\_\_  
Investigator: \_\_\_\_\_  
100 mg LY352727 (LOXO-305) LY352727  
Antal tabletter: 62 pr. flaske. Kun til oral brug.  
Skal tages efter forsøgslægens anvisninger.  
Tabletterne skal sluges hele. Tabletterne må ikke  
knuses, brækkes over eller tygges. Opbevares ved  
stuetemperatur (10 °C - 30 °C; 50 °F - 86 °F).  
Må ikke destrueres. Returner emballage og ubrugt  
lægemiddel til forsøgslægen. Opbevares utilgængeligt  
for børn. Kun til brug ved klinisk forsøg.

Label ID #: LIL10962PN13

Label Description: Denmark (Danish) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

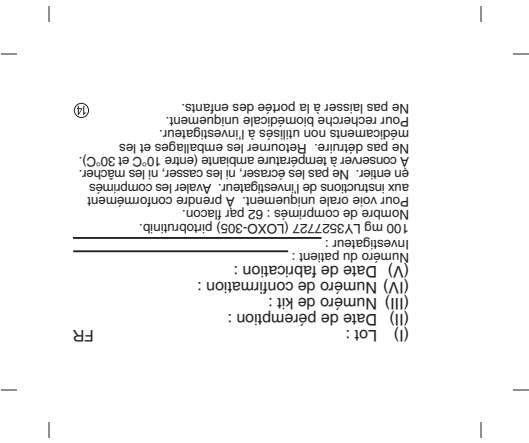
Client Approval: \_\_\_\_\_

IPI: \_\_\_\_\_ **SIGNATURE ON FILE**



by Thermo Fisher Scientific

# LABEL PROOF



(I) Lot :  
 (II) Date de péremption :  
 (III) Numéro de kit :  
 (IV) Numéro de confirmation :  
 (V) Date de fabrication :  
 (VI) Numéro du patient :  
 Investigateur :  
 100 mg LY352727 (LOXO-305) pirobutinib.  
 Nombre de comprimés : 62 par flacon.  
 Pour voie orale uniquement. À prendre conformément  
 aux instructions de l'investigateur. Avaler les comprimés  
 entiers. Ne pas les écraser, ni les mâcher,  
 À conserver à température ambiante (entre 10°C et 30°C).  
 Ne pas détruire. Retourner les emballages et les  
 médicaments non utilisés à l'investigateur.  
 Pour recherche biomédicale uniquement.  
 Ne pas laisser à la portée des enfants.

Label ID #: LIL10962PN14

Label Description: France (French) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: **SIGNATURE ON FILE** \_\_\_\_\_



by Thermo Fisher Scientific

# LABEL PROOF

(I) Ch.-B.: \_\_\_\_\_  
 (II) Verwendbar bis: \_\_\_\_\_  
 (III) Paket-Nr.: \_\_\_\_\_  
 (IV) Bestätigungs-Nr.: \_\_\_\_\_  
 (V) Herstellungsdatum: \_\_\_\_\_  
 (VI) Paten-Nr.: \_\_\_\_\_  
 100 mg L352727 (LOXO-305) Pirobutamid.  
 Anzahl Tabletten: 62 je Flasche. Zum Einnehmen.  
 Nach Anweisung des Pflanzes einnehmen. Tabletten  
 unzerkaut einnehmen, nicht öffnen, zerdrücken oder  
 zerkaen. Bei Raumtemperatur lagern (10°C - 30°C).  
 Nicht vernichten. Verpackung und unverbrauchtes  
 Arzneimittel dem Pflanz zurückgeben.  
 Zur klinischen Prüfung bestimmt. Arzneimittel für Kinder  
 unzugänglich aufbewahren. CRO: CVIA RDS GmbH  
 Unterschweinstiege 2-14, 60549 Frankfurt am Main,  
 © DEUTSCHLAND +49 (0) 69 6604 0

**Label ID #:** LIL10962PN15

**Label Description:** Germany (German) (5 pt.)

**Protocol #:** J2N-MC-JZNX

**Label Designed By:**

**Label Updated By:**

**Template ID #:** TCN12501

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ *SIGNATURE ON FILE*



(I) Ταμπά :  
 (II) Ημερομηνία λήξης:  
 (III) Αριθμός συσκευασίας:  
 (IV) Αριθμός επιβάρυνσης:  
 (V) Ημερομηνία παραγωγής:  
 Αριθμός αδελφός:  
 Επωνυμία:  
 100 mg LY352727 (LOXO-305) LY352727.  
 Αριθμός δοσίων: 62 ανά φιάλη. Μόνο για από του στόματος χρήση. Να αμφιβάλλεται αυτών με τις οδηγίες του εγχειριδίου. Καταστήτε να δοκίμασα φιαλάκι σε θερμοκρασία δωματίου (10°C - 30°C). Μην τα βυθίζετε, μην τα στείρετε και μην τα μασάτε. Μην το καταστρέψετε. Επιστρέψτε τη συσκευασία και το μη χρησιμοποιηθέν φάρμακο στον ερευνητή. Μόνο για χρήση σε κλινική μελέτη. Να διατηρείται σε μέρος που δεν φέδουν και δεν βρέθουν τα παιδιά.

**Label ID #: LIL10962PN16**

**Label Description: Greece (Greek) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**

(I) Gy.sz.:  
(II) Lejárati idő:  
(III) Csomagszám:  
(IV) Ellenőrző szám:  
(V) Gyártás dátuma:  
Bejegyzési szám:  
100 mg LY362777 (LOXO-305) pirbortinib.  
100 mg LY362777 (LOXO-305) pirbortinib.  
Tabletták száma: 62 lvegenként, kizárólag szájon  
át történő alkalmazásra. A vizsgálatvezető utasításai  
szint kell bevenni. A tablettát egészen nyelje le.  
Nem szabad részezni, szétlőni vagy szétvágni.  
Szobahőmérsékleten (10°C - 30°C) tárolandó.  
Tilos megsemmisíteni. A csomagolást és a fel nem  
használt gyógyszert a vizsgálatvezetőhöz kell visszaküldeni.  
Csak klinikai vizsgálat céljára használható.  
Ⓜ A gyógyszer gyermekektől elzárva tartandó!

HU

Label ID #: LIL10962PN17

Label Description: Hungary (Hungarian) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: \_\_\_\_\_ **SIGNATURE ON FILE**

(i) Lot: IN  
 (ii) Expiry Date:  
 (iii) Package Number:  
 (iv) Confirmation Number:  
 (v) Manufacturer Date:  
 (vi) Patent number:  
 Investigator:  
 100 mg LY352727 (LOXO-305) pibrotinib.  
 Tablet count: 62 per bottle. For oral use only.  
 Take as directed by investigator. Swallow tablets whole.  
 Do not crush, break or chew. Store at room temperature  
 (10°C - 30°C). Do not destroy. Return packaging  
 and unused medication to the investigator.  
 Keep out of reach of children. For Clinical Studies Only.  
 Manufacturer: Lilly del Caribe, Inc. 126 KM 65th Infantry  
 Road (PR01) Carolina, Puerto Rico (PR) 00985 USA ®

**Label ID #: LIL10962PN18**

**Label Description: India (English) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**

(I) Lot: IL  
(II) Expiry Date:  
(III) Package Number:  
(IV) Confirmation Number:  
(V) Manufacture Date:  
Investigator: \_\_\_\_\_  
Patient number: \_\_\_\_\_  
100 mg LY3027737 (LOXO-305) pirtobrutinib  
Tablet count: 62 per bottle. For oral use only.  
Take as directed by investigator. Swallow tablets whole.  
Do not crush, break or chew. Store at room temperature  
(10°C - 30°C; 50°F - 86°F). Do not destroy.  
Return packaging and unused medication to the investigator.  
**For clinical trial use only.**  
® Keep out of reach of children.

Label ID #: LIL10962PN19

Label Description: Israel (English) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: \_\_\_\_\_ **SIGNATURE ON FILE**

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 תאריך יצירה: 03/02/12

**47851011, LG1A, 771.**

**Техническое наименование**

מידע: המידע המופיע על התווית הוא באחריות היצרן. המידע אינו מהווה אחריות או זמן לטיפול. המידע אינו מהווה ייעוץ או מידע מדויק. המידע אינו מהווה אחריות או זמן לטיפול. המידע אינו מהווה ייעוץ או מידע מדויק.

תאריך: 03/02/12

תאריך: 03/02/12

תאריך: 03/02/12

תאריך: 03/02/12

תאריך: 03/02/12

**Label ID #: LIL10962PN20.1**

**Label Description: Israel (Hebrew) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By: Bolin, Kathleen**

**Label Updated By: Bolin, Kathleen**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ *SIGNATURE ON FILE* \_\_\_\_\_



by Thermo Fisher Scientific

### LABEL PROOF

(I) Lotto:  
 (II) Data di scadenza:  
 (III) Numero della confezione:  
 (IV) Numero di conferma:  
 (V) Data di produzione:  
 (VI) Numero del paziente:  
 Sperimentatore:  
 100 mg LY352727 (LOXO-305) piribrutinib.  
 Quantità delle compresse: 62 per flacone.  
 Solo per uso orale. Assumere secondo le indicazioni fornite dal medico sperimentatore. Deglutire le compresse intere. Non schiacciare, rompere o masticare. Conservare a temperatura ambiente (15°C - 30°C). Non distruggere. Resettare le confezioni e il farmaco non utilizzato al medico sperimentatore. Solo per sperimentazione clinica. Tenere fuori dalla portata dei bambini. Non per la vendita né per la rivendita.

Label ID #: LIL10962PN21

Label Description: Italy (Italian) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: \_\_\_\_\_ **SIGNATURE ON FILE**

(I) 製造番号: \_\_\_\_\_  
(II) 有効期限: \_\_\_\_\_  
(III) 薬剤番号: \_\_\_\_\_  
(IV) 確認番号: JP \_\_\_\_\_  
(V) 製造日: \_\_\_\_\_  
試験担当者: \_\_\_\_\_  
100 mg LY362727 (LOXO-305)  
レルトアルチニフ。錠剤数: 62  
1ストルあたり。経口剤。試験担当医師の指示に従い服用すること。錠剤はそのまま飲み込むこと。砕いたり、割ったり、噛んだりしないこと。貯蔵方法: 10°C~30°C。残った薬剤及び空容器は回収しますので、保管しておいて下さい。治療用。小児の手の届かない場所に保管して下さい。Loxo Oncology, Inc. 米国 治療  
国内管理人: 日本エーライリ株式会社 神  
戸市中央区磯上通5丁目1番 28号 ②

**Label ID #: LIL10962PN22**

**Label Description: Japan (Japanese) (6 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***

(I) Lote: \_\_\_\_\_  
 (II) Fecha de caducidad: \_\_\_\_\_  
 (III) Número de paquete: \_\_\_\_\_  
 (IV) Número de confirmación: \_\_\_\_\_  
 (V) Fecha de fabricación: \_\_\_\_\_  
 (VI) Número de paciente: \_\_\_\_\_  
 Investigador: \_\_\_\_\_  
 100 mg LY362777 (LOXO-305) pirbortinib.  
 Cantidad de comprimidos: 62 por frasco. Únicamente para  
 uso oral. Tomar según las indicaciones del investigador.  
 Tagar las tabletas enteras. No tragar, romper ni masticar.  
 Conservar a temperatura ambiente (17°C - 30°C).  
 No destruir. Devolver los empaques y medicamentos no  
 usados al investigador. Exclusivamente para estudios  
 clínicos. Mantener fuera del alcance de los niños.  
 Fábrica: Lilly del Caribe, Inc. 12.6 KM 65th Infantry Road  
 © (F01) Carolina, Puerto Rico (PR) 00985 USA

**Label ID #: LIL10962PN23**

**Label Description: Mexico (Spanish) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**


**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**



(I) Lot:  
(II) Vervaldatum:  
(III) Verpakingsnummer:  
(IV) Bevestigingsnummer:  
(V) Productiedatum:  
(VI) Palatinnummer:  
Onderzoeker:  
100 mg LY352727 (LOXO-305) pirobutinib.  
Aantal tabletten: 62 per fles. Uitsluitend voor oraal gebruik.  
Inname zoals voorgeschreven door de onderzoeker.  
Tabletten moeten in hun geheel worden ingenomen.  
Niet verkrijgen, breken of kauwen.  
Bewaren bij kamertemperatuur (10°C - 30°C).  
Niet vernietigen. Verpakking en ongebruikte medicatie  
terugbrengen naar de onderzoeker.  
Uitsluitend bestemd voor klinisch onderzoek.  
Buiten het bereik en zicht van kinderen houden. 

**Label ID #:** LIL10962PN24

**Label Description:** Netherlands (Netherlands) (5 pt.)

**Protocol #:** J2N-MC-JZNX

**Label Designed By:**

**Label Updated By:**

**Template ID #:** TCN12501

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***

(I) Nr serii:  
(II) Termin ważności:  
(III) Numer opakowania:  
(IV) Numer potwierdzenia:  
(V) Data produkcji:  
Numer pacjenta:  
Badacz:  
100 mg LY362727 (LOXO-305) LY362727.  
Liczba tabletek: 62 na butelkę. Wyjście do podania  
dostępnego. Przyjmować zgodnie z zaleceniami badacza.  
Tabletki połykać w całości. Nie kruszyć.  
nie żuć ani nie żuć. Przechowywać w temperaturze  
pokojowej (10°C – 30°C). Nie niszczyć.  
Opakowanie i niezutyty lek zwrócić badaczowi.  
Wyjście do użytku w badaniu klinicznym.  
© Lek przechowywać w miejscu niedostępnym dla dzieci.

Label ID #: LIL10962PN25

Label Description: Poland (Polish) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: \_\_\_\_\_ **SIGNATURE ON FILE**

RO

(i) Lot:  
(ii) Data expirării:  
(iii) Număr ambalaj:  
(iv) Număr de confirmare:  
(v) Data de fabricație:  
Număr pacient:  
Investigator:  
100 mg LY352727 (LOXO-305) LY352727.  
Număr comprimate: 62 per flacon. Numai pentru  
administrare orală. A se lua conform instrucțiunilor  
investigatorului. A se înghiți comprimatele întregi.  
A nu se sparge, a nu se strămuța sau a nu se mesteca.  
A se păstra la temperatura camerei (10°C – 30°C).  
A nu se distruge. A se returna ambalajul și  
medicamentele neutilizate la investigator.  
ATENȚIE A se folosi numai în studiul clinic.  
A nu se lăsa la îndemâna copiilor.

**Label ID #: LIL10962PN26**

**Label Description: Romania (Romanian) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***



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**LABEL PROOF**

(I) Šarža:  
(II) Dátum expirácie:  
(III) Číslo balenia:  
(IV) Číslo potvrdenia:  
(V) Dátum výroby:  
Číslo pacienta: \_\_\_\_\_  
Skladujte lekárske: \_\_\_\_\_  
100 mg LV3527Z7 (LOXO-305) LV3527Z7  
Pocet tablet 62 v jednej fľaši. Len na perorálne použitie.  
Používajte podľa pokynov skúsajúceho lekára.  
Tablety prehĺtajte cele. Nedrviť, neštiepať ani nežúčať.  
Uchovávať pri izbovej teplote (10°C – 30°C).  
Neikkovávať. Obal spolu s nepoužitým liekom vrátiť  
skúsajúceho lekárovi. Uchovávať mimo dosahu a  
dohľadu detí. VZORKA NA KLINICKE SKÚŠANIE.

SK

**Label ID #: LIL10962PN27**

**Label Description: Slovakia (Slovak) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***

(I) 문득: (IV) 확인 번호: KR  
 (II) 사용(유효)기간: (V) 제조일:  
 (III) 포장 번호:  
 환자 번호:  
 연구자: \_\_\_\_\_  
 100 mg LY352727 (LOXO-305) LY352727.  
 정제 개수: 62 병입. 연구 복용에 한함.  
 연구자의 지시대로 복용하십시오. 잔제를  
 으개거나 쪄개거나 씹지 말고, 물째로  
 삼키십시오. 실온 (10°C - 30°C; 50°F - 86°F)  
 에서 보관하십시오. 파기하지 마십시오.  
 포장과 미사용 약물은 연구자에게 반납하십시오.  
 영상이용. 이 라벨이 손이 닿지 않는 곳에  
 부착하십시오. 한국 로컬 리

**Label ID #: LIL10962PN28.1**

**Label Description: South Korea (Korean) (6 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By: Bolin, Kathleen**

**Label Updated By: Bolin, Kathleen**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**

(I) Lote:  
(II) CAD:  
(III) Número de envase:  
(IV) Número de confirmación:  
(V) Fecha de fabricación:  
(VI) Número de paciente:  
Investigador:  
100 mg LY352727 (LOXO-305) LY352727  
Número de comprimidos: 62 por frasco.  
Para uso exclusivo por vía oral. Tomar según las indicaciones del investigador. Tagar los comprimidos enteros. No triturar, romper ni masticar. Conservar a temperatura ambiente (entre 10°C y 30°C). No destruir. Devolver los envases y medicamentos no usados al investigador. Para uso exclusivo en ensayos clínicos.  
© Mantener fuera del alcance de los niños.

**Label ID #: LIL10962PN29**

**Label Description: Spain (Spanish) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***

(I) 批號: \_\_\_\_\_  
 (II) 失效日期: \_\_\_\_\_  
 (III) 包裝編號: \_\_\_\_\_  
 受試者編號: \_\_\_\_\_  
 試驗醫師: \_\_\_\_\_  
 100 mg LY362727 (LOXO-305) LY362727。  
 錠劑數量: 62 每個藥瓶。僅供口服使用。  
 根據試驗主持人指示服用。將整個錠劑吞服。  
 請勿壓碎、破壞或咀嚼。儲存於室溫  
 (10°C - 30°C)。請勿精緻。請將包裝和未用  
 藥物歸還予試驗醫師。臨床試驗專用。  
 請勿存放於兒童可觸及的地方。 ©

**Label ID #: LIL10962PN30**

**Label Description: Taiwan (Chinese) (6 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**

(I) Lot: TW  
(II) Expiry Date:  
(III) Package Number:  
(IV) Confirmation Number:  
(V) Manufacture Date:  
Patient number: \_\_\_\_\_  
Investigator: \_\_\_\_\_  
100 mg LY3027727 (LOXO-305) pitobutrinib.  
Tablet count: 62 per bottle. For oral use only.  
Take as directed by investigator.  
Swallow tablets whole. Do not crush, break or chew.  
Store at room temperature (10°C - 30°C; 50°F - 86°F).  
Do not destroy. Return packaging and unused  
medication to the investigator. For clinical trial use only.  
Ⓢ Keep out of reach of children.

**Label ID #: LIL10962PN31**

**Label Description: Taiwan (English) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**





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**LABEL PROOF**

(I) Lot: TR  
(II) Son Kullanma Tarihi:  
(III) Paket Numarası:  
(IV) Konfirmasyon Numarası:  
(V) Üretim Tarihi:  
Hasta numarası: \_\_\_\_\_  
Araştırma: \_\_\_\_\_  
100 mg LY352727 (LOXO-305) LY352727  
Tablet sayısı: 62 her bir şişe için. Yalnız oral kullanım  
içindir. Araştırmanın belirliği şekilde alınır.  
Tabletlerin bütün olarak yutulması, Ezme, kırma ya  
ya değdirmeyiniz. Oda sıcaklığında (10°C -  
30°C) saklayınız. İmha etmeyiniz. Ambalajları ve  
kullanılmamış ilaçları araştırmacıya iade ediniz.  
Çocukların erişemeyeceği bir yerde saklayınız.  
Yalnızca klinik araştırma kullanımını içindir.

**Label ID #: LIL10962PN32**

**Label Description: Turkey (Turkish) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ **SIGNATURE ON FILE**

(I) Lot: GB  
(II) Expiry Date:  
(III) Package Number:  
(IV) Confirmation Number:  
(V) Manufacture Date:  
Investigator: \_\_\_\_\_  
100 mg LY352727 (LOXO-305) pibrotinib.  
Tablet count: 62 per bottle. For oral use only.  
Take as directed by investigator. Swallow tablets whole.  
Do not crush, break or chew. Store at room temperature  
(10°C - 30°C; 50°F - 86°F). Do not destroy. Return  
packaging and unused medication to the investigator.  
© For clinical trial use only. Keep out of reach of children.

Label ID #: LIL10962PN33

Label Description: United Kingdom (English) (5 pt.)

Protocol #: J2N-MC-JZNX

Label Designed By:

Label Updated By:

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: \_\_\_\_\_ **SIGNATURE ON FILE**

(i) Lot: \_\_\_\_\_  
(ii) Expiry Date: \_\_\_\_\_  
(iii) Package Number: \_\_\_\_\_  
(iv) Confirmation Number: \_\_\_\_\_  
(v) Manufacture Date: \_\_\_\_\_  
(vi) Patient number: \_\_\_\_\_  
Investigator: \_\_\_\_\_  
100 mg LY3627727 (LOXO-305) pibrotinib.  
Tablet count: 62 per bottle. For oral use only.  
Take as directed by investigator. Swallow tablets whole.  
Do not crush, break or chew. Store at room temperature  
(10°C - 30°C; 50°F - 86°F). Do not destroy. Return  
packaging and unused medication to the investigator.  
Keep out of reach of children. CALTONE, New drug -limited  
by Federal (or United States) law to investigational use. ©

**Label ID #: LIL10962PN34**

**Label Description: United States of America (English) (5 pt.)**

**Protocol #: J2N-MC-JZNX**

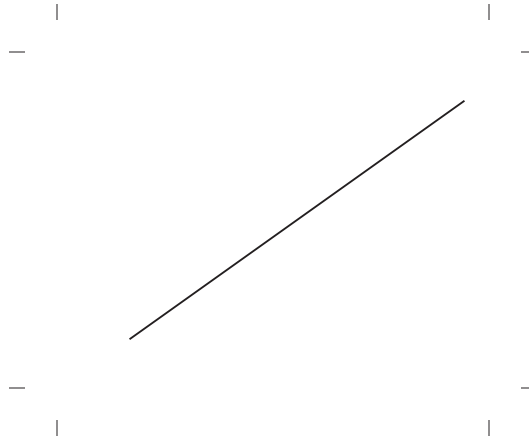
**Label Designed By:**

**Label Updated By:**

**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***



**Label ID #:** LIL10962PN35

**Label Description:** Blank

**Protocol #:** J2N-MC-JZNX

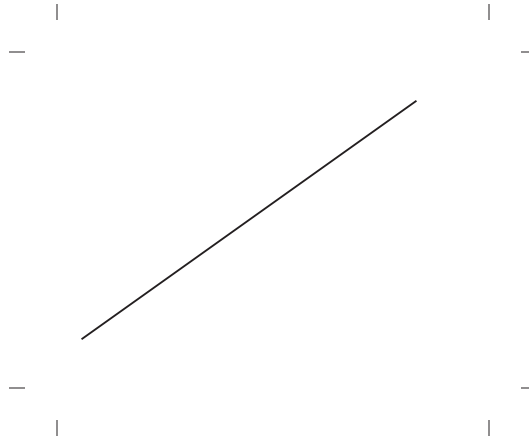
**Label Designed By:**

**Label Updated By:**

**Template ID #:** TCN12501

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***



**Label ID #: LIL10962PN36**

**Label Description: Blank**

**Protocol #: J2N-MC-JZNX**

**Label Designed By:**

**Label Updated By:**

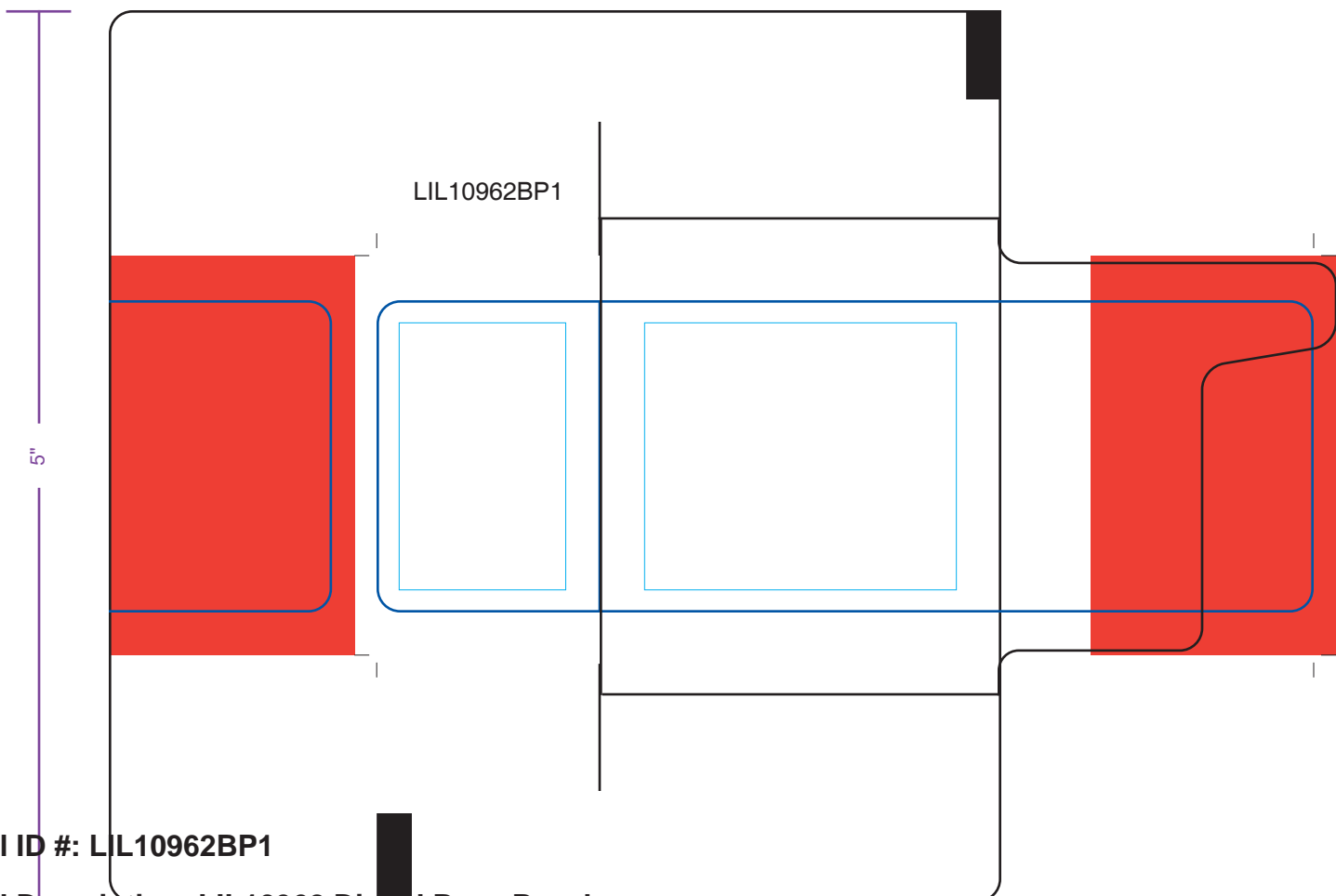
**Template ID #: TCN12501**

**Client Approval:** \_\_\_\_\_

**IPI:** \_\_\_\_\_ ***SIGNATURE ON FILE***

**LABEL PROOF**

Repeat = 5-1/2"



Label ID #: LIL10962BP1

Label Description: LIL10962 Digital Base Panel

Protocol #: J2N-MC-JZNX

Label Designed By: Santana, Guillermo

Label Updated By: Santana, Guillermo

Template ID #: TCN12501

Client Approval: \_\_\_\_\_

IPI: \_\_\_\_\_ **SIGNATURE ON FILE**