IPHEPHA LOLWAZI LOMTHATHI-NXAXHEBA NEFOMU YEMVUME ESEKELWE ELWAZINI

Isihloko soPhononongo:

Amaziko onyango awohlukeneyo, olwenziwa kumaziko awohlukeneyo, olungafihlwanga, olunamaqela akhiwa ngendlela engahlelwanga, olunamathamo awohlukeneyo, iindlela zonyango ezimbini, amaxesha amabini okudlulela kwelinye, oluthelekisa ukufana kweyeza eliyimveliso eVavanywayo [i-Amphotericin B (i-Liposome esetyenziswa kwisitofu) i-50 mg/vial, Cipla Ltd., India] kunye nemveliso eyiReferensi [i-AmBisome® (i-Amphotericin B) i-Liposome esetyenziswa kwisitofu eyi-50 mg/vial), Gilead life sciences, USA] kwizigulana ezingabantu abadala abanosuleleko lomngundo.

Inombolo yeProtokholi.: IPD/CLI/15/003 Uhlelo 04, lomhla: 10 Februwari 2016

Uhlelo lwe-ICD: 04, lomhla we-20 Aphrili 2016

Inombolo yoHluzo yoMthathi-nxaxheba: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Oonobumba bokuqala baMagama oMthathi-nxaxheba: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Oonobumba Bokuqala Bamagama Elokuqala-Eliphakathi-Elokugqibela)

Igama likaGqirha woLingo: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Umphandi oyiNtloko)

Idilesi yeSiza: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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ISIMEMO SOKUTHATHA INXAXHEBA

Uyamenywa ukuba uthathe inxaxheba kolu phononongo lophando lweyeza lophononongo elihlolwayo nelaziwa ngokuba yi-Amphotericin B (i-Liposome esetyenziswa kwisitofu) eliyi-50mg/vial, njengoko ufunyaniswe unosuleleko lomngundo.

Olu xwebhu lwemvume luchaza ulingo lophando kunye nendima yakho kulingo olu. Nceda ulufunde ngononophelo kwaye uluqondisise olu xwebhu. Olu xwebhu lunokuba namagama onokuthi ungawaqondisisi; ugqirha wakho wophononongo uya kukunceda ekubeni uwaqonde amagama la. Ungaxoxa malunga nokuthatha kwakho inxaxheba kunye nosapho lwakho, abahlobo kunye nogqirha wakho ngaphambi kokuba wenze isigqibo kwaye uvumelekile ukuba uthathe ixesha olidingayo nokuba lingakanani na ngaphambi kokuba uvume ukuthabatha inxaxheba kolu lingo.

NGUBANI OQHUBA OLU PHONONONGO?

Uphononongo luqhutywa yi-Quintiles egameni le-Cipla Ltd., India (Umxhasi). Umxhasi uqulunqe indibaniso yovavanyo ye-Amphotericin B (i-Liposome esetyenziswa kwisitofu) eyi-50 mg/vial.

UKUTHATHA INXAXHEBA KWAKHO KOKOKUZITHANDELA

Ukungena kulingo lophando kukuzithandela okupheleleyo. Ukhululekile ukuba ukhethe ukuba ungabi yinxalenye kolu lingo okanye uyeke ukuthatha inxaxheba nangalo naliphi na ixesha kwye akuyi kubakho nasiphi na isohlwayo kuwe. Akudingeki ukuba unike isizathu ngokurhoxa kwakho ekuthabatheni inxaxheba kuphononongo. Ukuba ngaba uthe wayeka, kuya kubaluleka kuwe ukuba ubaxelele abasebenzi bolingo kwaye ulandele nayiphi na imiyalelo oya kuthi uyinikwe ukuze kukhuseleke ukurhoxa kwakho kwiyeza lolingo.

YINTONI OKUFANELE UYAZI MALUNGA NOLU LINGO LOPHONONONGO?

• Olu lingo luquka uphando ngeyeza lophononongo elihlolwayo.

• Bangama-44 ubuncinane abathathi-nxaxheba abaza kuthatha inxaxheba kolu phononongo. Bamalunga ne-15 abathathi-nxaxheba abasuka kwiziza ezi-2-4 eMzantsi Afrika abaza kuthatha inxaxheba

• Ugqirha wakho wolingo ungambuza imibuzo malunga nayo nantoni na ongayiqondiyo ngoku okanye kwixesha elizayo.

• Ukuba ngaba ugqirha wakho wolingo ayinguye ugqirha oqhelekileyo wosapho lwakho, ukwenzela ukhuseleko lwakho, kufuneka umxelele ugqirha oqhelekileyo wosapho lwakho ukuba uthatha inxaxheba kulingo lophando. Nceda uxoxe ngayo nantoni na ekuxhalabisayo malunga noku kunye nogqirha wakho wolingo.

• Ngelixa ukolu lingo, iqela lolingo liya kuhlala likwazisa malunga nalo naluphi na ulwazi olutsha olufunyanisiweyo okanye olubonwe ngexesha lolingo nolunokuthi luchaphazele isigqibo sakho sokuba uqhubeke okanye urhoxe kulingo.

LITHINI IXESHA LOPHONONONGO LILONKE LOLINGO?

Ixesha lophononongo lilonke liya kuba malunga neentsuku ezingama-50 kuqukwe nexesha lohluzo. Ixesha lonyango liya kuthatha iintsuku ezili-10. Iinkcukacha zimi ngolu hlobo

• Uya kulandela inkqubo yohluzo ukuya kutsho kwiintsuku ezili- 10 ngaphambi kwethamo lokuqala.

• Ukuba ngaba ufunyaniswe ukulungele ukuthatha inxaxheba kuphononongo ngokweemfuno zophononongo, uya kunikwa iMveliso eHlolwayo [i-Amphotericin B (i-Liposome esetyenziswa kwisitofu) eyi-50 mg/vial] okanye iMveliso eyiReferensi [i-AmBisome® (i-Amphotericin B) Liposome esetyenziswa kwisitofu eyi-50 mg/vial),] efakwa emithanjeni ngokweshedyuli yokwabiwa ngokwamaqela ngendlela engahlelwanga ngosuku 01.

• Uya kufumana ithamo elilinganayo le-Amphotericin B lonyango ngeSitofu seLiposomal kumaxesha abekiweyo emva kweeyure ezingama-24 ixesha elingekho ngaphantsi kweentsuku ezili-10.

• Usenokufumana imveliso ehlolwayo okanye imveliso eyireferensi iintsuku ezi-5 (Usuku 1-5), uze emva koko utshintshelwe kolunye unyango iintsuku ezi-5 (Usuku 6-10).

Uya kulandelelwa ukuya kutsho kusuku lwesi-7 nosuku lwama-30 ukusuka ngosuku lokugqibela lokuthatha iyeza lophononongo (Usuku 17 noSuku 40 lophononongo) ukwenzela ukwenza iingxelo kunye nolandelelo lwe-AEs; ngomnxeba

.

YINTONI INJONGO YOLINGO LOPHANDO?

Injongo yolu lingo kukufumanisa iiprofayili ze-pharmacokinetic (olu luphononongo lokuhamba kweyeza emzimbeni, kuquka iinkqubo zokufunxwa, ukuhanjiswa, kunye nokukhutshwa kwalo\_ kwakunye nokuhlola ukufana kwesithako esisebenzayo seemveliso zeyeza ezi-2 ezineqondo elinye kunye nemeko yofunxo. Xa isibenza kulonto ijoliswe kuyo -- umzekelo, isamkeli engqondweni – iyeza elilelona elenziwe yinkampani yokuqala kunye nelo lifanayo lenziwe zezinye iiinkampani kufanele omabini agqithise umthamo olinganayo wesithako esisebenzayo kwindawo leyo lijoliswe kuyo) yemveliso eHlolwayo [i-Amphotericin B (i-Liposome esetyenziswa kwisitofu) eyi-50 mg/vial, Cipla Ltd, India] kunye naleyo yemveliso eyiReferensi [i-AmBisome® (i-Amphotericin B) Liposome esetyenziswa kwisitofu eyi-50 mg/vial), Gilead life sciences, USA] kubathathi-nxaxheba abangabantu abadala abanosuleleko lomngundo.

I-AmBisome® ibhaliswe eMzantsi Afrika ukuba isetyenziwe kusulelelo lomngundo, kodwa ke iyeza elihlolwayo lona (i-Amphotericin B) alibhaliswanga eMzantsi Afrika

UKUBA NGABA UGQIBA EKUBENI UTHATHE INXAXHEBA KOLU PHONONONGO

Ukuba ngaba uvumile ukuthatha inxaxheba kolu phononongo, kuza kufunyanwa imvume Esekelwe Elwazini (amaphepha ama-3 okugqibela ancanyathiselwe kolu xwebhu) kuwe njengesiqinisekiso sakho sokuthatha inxaxheba kolu phononongo. Ukuba ngaba awukwazi ukufunda/ukubhala, kuya kubakho ingqina elingakhethi cala ngalo lonke ixesha lenkqubo yemvume esekelwe elwazini lize likuchazele banzi ngeenkqubo zolingo kananjalo lisayine kwifomu yemvume.

INDLELA YOKUTHATHWA KWEYEZA

Ishedyuli yokuthathwa kwamathamo kolu phononongo iza kuhamba ngolu hlobo:

Ukuba ngaba ufunyaniswe ukulungele ukuthatha inxaxheba kuphononongo ngokweemfuno zophononongo, uya kunikwa iMveliso eHlolwayo [i-Amphotericin B (i-Liposome esetyenziswa kwisitofu) eyi-50 mg/vial] okanye iMveliso eyiReferensi [i-AmBisome® (i-Amphotericin B) i-Liposome esetyenziswa kwisitofu eyi-50 mg/vial),] elihlatywa emithanjeni (ifakwa ngokuhlaba ngenalithi kwimithambo yakho) ngokweshedyuli yokwabiwa ngokwamaqela ngendlela engahlelwanga ngosuku 01.

Uya kufumana ithamo elilinganayo le-Amphotericin B lonyango ngeSitofu seLiposomal kumaxesha abekiweyo emva kweeyure ezingama-24 ixesha elingekho ngaphantsi kweentsuku ezili-10.

Ukuba ngaba udinga ukutshintshwa kwamathamo ngezi ntsuku zili-10 uya kukhutshwa kuphononongo.

• Akuyi kubakho xesha lokukhutshwa kwamayeza emzimbeni phakathi kwamanyango amabini.

Ithamo lemveliso ehlolwayo okanye leyo iyireferensi iya kuba lithamo elifanelekileyo nelicetyiswe ngumphandi ukuba liya kumelana neemfuno zakho.

UKULALISWA ESIBHEDLELE:

Uya kufakwa kwixesha lohluzo ukuya kutsho kwiintsuku ezili-10 phambi kosuku loku-1. Ukuba ngaba ufunyaniswe ukuba ukulungele ukufumana ithamo, uya kunikwa ithamo lovavanyo (T) okanye elereferensi (R) ngosuku loku-1, ngokweshedyuli yokwabiwa ngokwamaqela ngendlela engahlelwanga. Uya kungeniswa kwiziko lonyango ubuncinane iiyure ezili-13 ngaphambi kokunikwa ithamo ngosuku loku-1. Wakuba ungenisiwe kweli ziko uya kuhlala kulo ixesha lamanyango omabini.

Uhluzo:

Uya kulandela inkqubo yohluzo ukuya kutsho kwiintsuku ezili-10 ngaphambi kokuqala konyango lophononongo ngosuku loku-1.

Usuku 01, 02, 03, 04, 05 (Ixesha I)

Uya kungeniswa kwiziko lonyango ubuncinane iiyure ezili-13 ngaphambi kokunikwa ithamo ngosuku loku-01. Wakuba ungenisiwe kweli ziko uya kuhlala kulo ixesha lamanyango omabini.

Ngazo zonke iintsuku zokunikwa ithamo unyango lophononongo luya kuqaliswa kwiiyure ezi-2 emva kokuba ufumene isidlo esiqhelekileyo (esingenamafutha maninzi) sakusasa.

Imveliso ehlolwayo okanye eyireferensi, ngokweshedyuli yokwabiwa ngokwamaqela ngendlela engahlelwanga, iya kunikezwa ngokuhlatywa ngenaliti kwimithambo, kusetyenziswa isixhobo esilawulwayo sokufaka iyeza, kwisithuba seeyure ezi-2 (± 5 imizuzu).

Iisampuli zegazi ze-pharmacokinetic zangaphambi kwethamo (ukuhlola ukusebenza kwe-pharmacokinetic) ziya kuthathwa ngeentsuku u- 3, 4 no-5; zize iisampuli zegazi zasemva kwethamo zithathwe ngosuku lwesi-5 ukuya kwelesi-6 ngokweshedyuli yokuthathwa kweesampuli zegazi ze-pharmacokinetic.

Ixesha lokukhutshwa kwamayeza egazini: akuyi kubakho xesha lokukhutshwa kwamayeza egazini phakathi kwexesha loku-I nexesha lesi-II.

Usuku 6, 7, 8, 9 nele-10 (Ixesha II)

Ngazo zonke iintsuku zokunikwa ithamo unyango lophononongo luya kuqaliswa kwiiyure ezi-2 emva kokuba ufumene isidlo esiqhelekileyo (esingenamafutha maninzi) sakusasa.

Imveliso ehlolwayo okanye eyireferensi, ngokweshedyuli yokwabiwa ngokwamaqela ngendlela engahlelwanga, iya kunikezwa ngokuhlatywa ngenaliti kwimithambo, kusetyenziswa isixhobo esilawulwayo sokufaka iyeza, kwisithuba seeyure ezi-2 (± 5 imizuzu).

Iisampuli zegazi ze-pharmacokinetic zangaphambi kwethamo ngeentsuku 8, 9 nele-10 kunye neesampuli zegazi ze-pharmacokinetic zasemva kwethamo ngosuku lwe-10 ukuya kwele-11 ziya kuthathwa ngokweshedyuli yokuthathwa kweesampuli ze-PK (pharmacokinetic).

“Utyelelo olungacwangciswanga - Ukuba ngaba unako nakuphi na ukungaphatheki okumandla okanye ukugula (okunxulumene okanye okunganxulumenanga nokuthatha inxaxheba kuphononongo okanye iyeza lophononongo) emva kokuba usayine le fomu ngexesha lophononongo, ungatyelela ugqirha wakho ngalo naliphi na ixesha ukusuka elingekho kumatyelelelo akho acwangcisiweyo”.

Imeko Yokutya Kwakho kunye Nezingavunyelwanga

Kufuneka uvume ukuba awuziyitya i-grapefruit okanye nantoni na eyenziwe ngayo; kwaye awuzusela utywala / iimveliso zotywala ubuncinane iiyure ezingama-48 ngaphambi kokufumana ithamo kude kuthathwe isampuli yegazi yokugqibela yexesha ngalinye lophononongo.

Kananjalo akufuneki uzitye iziqhamo zesitrasi okanye iimveliso zazo; iimveliso ezine-Xanthine (itshokholethi, iti, ikofu okanye isiselo se-cola); kananjalo ungatshayi okanye uthathe icuba okanye iimveliso ezinecuba ubuncinane iiyure ezingama-24 ngaphambi kokufumana ithamo kude kuthathwe isampuli yegazi yokugqibela yexesha ngalinye lophononongo.

Uya kunikwa ukutya okuqhelekileyo okungenamafutha maninzi yonke imihla ngexesha lophononongo ukuba ngaba akukho kuphazamisana nonakekelo lwakho. Kuya kudingeka ukuba ungatyi ubusuku bonke ubuncinane iiyure ezili-10 ngaphambi (kwesidlo sakusasa esiqhelekileyo esingenamafutha maninzi).

Uya kufumana unyango lophononongo iiyure ezi-2 emva kokugqiba completion isidlo sakusasa esiqhelekileyo (esingenamafutha maninzi) yonke imihla ngexesha lophononongo.

Unyango lwamayeza ahamba namanye ngezixubisiso zamafutha, ezifana nesondlo ezipheleleyo somzali (total parental nutrition (TPN)) ziya kuphetshwa, njengoko oko kunokuyitshintsha iprofayili ye-pharmacokinetic yeyeza lophononongo.

Amayeza Ahamba Namanye

Amayeza ahamba namanye (anefuthe kwi-PK ne-PD yamayeza ahlolwayo) nanikwa umthathi-nxaxheba kufuneka angaguquki ngexesha lonke lophononongo.

ISHEDYULI YOKUTHATHWA KWEESAMPULI ZEGAZI ZE-PHARMACOKINETICS

Iisampuli zegazi ziya kuthathwa ngendlela yokutofa kutsalwe emthanjeni, amaxesha amaninzi ophezulu engalweni. Ukuba ngaba kuyadingeka, zinokutsalwa nangendlela ekuthiwa yi-fresh vein puncture. Le nkqubo inokubangela ubuhlungu obungephi nokugruzuka kwindawo leyo kuhlatywe kuyo okanye kwenziwe i-vein puncture. Zingama-34 zizonke iisampuli zegazi eziya kuthathwa ukwenzela uhlolo lwe-pharmacokinetic ngexesha lophononongo lonke.

Iisampuli zakho ziya kugcinwa kwisiza sophononongo okanye kwilebhu yalapho endaweni. Iisampumi zeplasma ziya kuthunyelwa ukusuka kwisiza ukuya

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Iisampuli ziya kugcinwa malunga neenyanga ezi-6 emva kokuba lugqityiwe uphononongo.

Amaxesha okutsalwa kwegazi le-pharmacokinetic:

Isampuli yegazi yangaphambi kwethamo (Usuku 03 ukuya kuSuku 05 noSuku 08 ukuya kuSuku 10)

Zonke iisampuli zangaphambi kwethamo eziyi-6 mL (malinga netisipuni e-1) nganye ziya kutsalwa ngoko nangoko ngaphambi kweli thamo ngalinye nalapho kuya kuvunyelwa ukuphuma ecaleni kwemizuzu emi -5 ukutsho oko, ingekapheli imizuzu emihlanu yethamo ngalinye kwixesha ngalinye.

Iisampuli zegazi ezisemva kwethamo (Usuku 5 ukuya kusuku 6 kunye noSuku 10 ukuya kusuku 11):

Iisampuli zegazi ezisemva kwethamo eziyi- 05 mL nganye ziya kutsalwa kwi-1.333(iyure e-1 enemizuzu engama-20), i-1.667 (iyure e-1 enemizuzu engama-40), i-2.000\* (ukutsho oko, ekupheleni kwexesha lokufakwa kweyeza emthanjeni), i-2.333 (iiyure ezi-2 ezinemizuzu engama-20), i-2.667 (iiyure ezi-2 ezinemizuzu engama-40), i-3.000, i-3.500, i-4.000, i-5.000, i-6.000, i-8.000, i-12.000, i-16.000 neeyure ezingama-24.000 emva kwethamo. (iisampuli ezili-14 ixesha ngalinye).

\* Isampuli kufanele ithathwe ekupheleni kokufakwa kweyeza emthanjeni (iiyure ezi-2 ± imizuzu emi-5). Ukuba ngaba ixesha lokufakwa kweyeza emthanjeni liyedlula kwiiyure ezi-2 (+ imizuzu emi-5), uya kukhutshwa ke ngoko kuphononongo .

IGAZI EKUPHULUKENWE NALO LILONKE

Alikho ngaphezulu kwe-218 ± 10mL (i-3/4 yekomityi kunye neetisipuni ezi-2) kwisigulane ngasinye kumaxesha amabini ngale ndlela ilandelayo:

Iisampuli ze-PK ezingaphambi kwethamo (i-06 ml x amaxesha ama-6) = 36 mL (amacephe ama-2 kunye netisipuni e-1)

Iisampuli ze-PK ezisemva kwethamo (05 ml x amaxesha angama-28) = 140 mL (amacephe ali-10)

24 x 0.5 mL igazi elilahliweyo = 12 mL (iitisipuni ezi-2)

Ukwenzela uhluzo = 10 mL (iitisipuni ezi-2)

Uhlolo lokhuseleko ngaphambi kweXesha lesi-II = 10 mL (iitisipuni ezi-2)

Uhlolo lokhuseleko emva kophononongo = 10 mL (iitisipuni ezi-2)

Lilonke = 218 mL (¾ yekomityi)

AMANYATHELO OKHUSELEKO ONYANGO

Luxanduva lukagqirha wolingo [umphandi oyintloko] ukuqinisekisa ukuba ufumana ukubekelwa iliso kunye nonakekelo olwaneleyo ngexesha lophononongo ukuqinisekisa ukhuseleko olugqibeleleyo kunye nokuphatheka ngokukuko. Kulandela iimvavanyo zaselebhu/Kuya kwenziwa uphando ngexesha lophononongo ukuqinisekisa ukhuseleko lwakho.

Inkqubo yokhuseleko Amaxesha

Ukuxilongwa komzimba • Uhluzo,

• Usuku (-1) (isisekelo sexesha I),

• Usuku 05 (isisekelo sexesha II),

• Ekupheleni kophononongo

Ubude bomzimba • Uhluzo

Ubunzima bomzimba • Uhluzo,

• Ekupheleni kophononongo

IiMpawu eziBalulekileyo: Uxinzelelo lwegazi, ukubetha kwentliziyo, ubushushu bomzimba • Uhluzo,

• Usuku (-1) (isisekelo sexesha I),

• Usuku 1, 2,3,4,5 (ixesha I, Ngaphambi kwethamo, iiyure ezi-4, 8, nezili-12 emva kwethamo),

• Usuku 5 (isisekelo sexesha II)

• Usuku 6, 7,8,9,10 (ixesha II, Ngaphambi kwethamo, iiyure ezi-4, 8, nezili-12 emva kwethamo),

• Ekupheleni kophononongo

Uvavanyo lwe-ECG • Uhluzo,

• Ekupheleni kophononongo

Uvavanyo lwe-ECHO • Uhluzo

I-X-ray (yesifuba) • Uhluzo (i-X-ray ethathwe ukuya kutsho kwiinyanga ezi-3 ngaphambi kohluzo iya kwamkelwa).

I-hematology; ikhemistri yegazi; i-urinalysis • Uhluzo,

• Usuku (-1) (isisekelo sexesha I),

• Usuku 05 (isisekelo sexesha II),

• Ekupheleni kophononongo

Uvavanyo lokukhulelwa kwiNcindi Yegazi (Kubathathi-nxaxheba basetyhini kuphela) • Uhluzo,

• Usuku (-1) (isisekelo sexesha I)

• Ekupheleni kophononongo

Iimvavanyo ze-serology eziqukwa ukujongwa kweHepatitis (neziquka iindidi u-B&C) kunye neHIV. • Uhluzo

Inqobo yokufumanisa isifo yonyango olu-empirical (unyango olusetyenziswa ngaphambi kokuba kwenziwe ukufunyaniswa okuqinisekileyo kwesifo) kosuleleko oluqikelelwayo lomngundo kubathathi-nxaxheba aba-febrile, neutropenic  Kuhluzo

Ubungqina obubhaliweyo be:

• Neutropenia: buchazwa njengobalo lwe-neutrophil oluqinisekileyo (ANC) < 5,000/µL (ilingana ne- < 0.5 x 109/L).

• Febrile: ichazwa njengobushushu obuyi ≥ 38.3°C kwiiyure ezingama-48 zokugqibela okanye ubenokuvuka ngokutsha komkhuhlane (imilinganiselo emi-2, iiyure ezi-3 ezahlukeneyo) emva kokunyangwa okokuqala komkhuhlane ngonyango lwezibulala-zintsholongwane

Inqobo yokufumanisa isifo yoNyango lwe-Cryptococcal Meningitis (usuleleko lomngundo lweethishu ezigqume ingqondo kunye nomnqonqo) kubathathi-nxaxheba abane-HIV  Kuhluzo

• Abathathi-nxaxheba abane-HIV abafunyaniswe bene-Cryptococcal Meningitis.

• Ubungqina obubhaliweyo bokubakho kwencindi ye-cerebrospinal (CSF) OKANYE incindi yegazi OKANYE i-plasma cryptococcal antigen (CrAg).

Inqobo yokufumanisa isifo yaBathathi-nxaxhebaabanoHlobo lwe-Aspergillus, uhlobolwe- Candida kunye/okanye usuleleko lweentlobo ze-Cryptococcus kwi-Amphotericin B deoxycholate, okanye kubathathi-nxaxheba apho ukungasebenzi kakuhle kwezintso okanye ukungamkeleki kwetyhefu kungakuvumeliyo ukusetyenziswa kwe-Amphotericin B deoxycholate.  Kuhluzo

• Ubungqina obubhaliweyo bokubakho kwezinto ze-Aspergillus okanye i-Candida okanye i-cryptococcus kwithishu, egazini, okanye nayiphi na enye incindi yomzimba.

Iziphumo ezingalindelekanga: Ukusuka kwixesha lokufumana iyeza lophononongo okokuqala kude kube Sekupheleni koPhononongo. Iziphumo Ezisecaleni ezenzeka ngaphambi kokuqalisa occurring iyeza lophononongo kodwa emziya kubhalwa.

Amayeza ahamba namanye/ Amanyango amakhulu angaphandle kwamayeza Ukusuka kusuku loku-1 lophononongo kude kube Sekupheleni koPhononongo.

Amayeza athathwe ngaphambi kwethamo lokuqala Onke amayeza athathwe kwinyanga enye, (kuquka neevithamini) athathwe kwiintsuku ezili-10 ngaphambi kokufumana ithamo (okanye iSisekelo xa kuchaziwe) aya kubhalwa

UVAVANYO LWE-HIV

Kuya kudingeka ukuba wenze uvavanyo lwe-HIV. Lonke ulwazi olunxulumene nolu vavanyo lwe-HIV kuya kuxoxwa ngalo kunye nawe kwaye kuya kudingeka ukuba usayine ifomu esecaleni yemvume esekelwe elwazini ye-HIV. Ugqirha wakho uza kuxoxa nawe malunga noku.

BUTHINI UBUNGOZI KUNYE NOKUNGAPHATHEKI KAKUHLE BOLINGO?

Njengawo onke amayeza, i-Amphotericin B inokubangela iziphumo ezisecaleni, nangona ingesinguye wonke umntu ozifumanayo.

Phakathi kwezona zimandundu kunye/okanye ukwalisa okukhulu okuchaziweyo malunga nokusetyenziswa kwe-Amphotericin B ukuza kufuka ngoku yingqele, ukutsho oko, ukwalisa, isicaphucaphu, ukugabha nokwehla kwepotesyam.

Ezi zehlo zimandundu zilandelayo nazo ziye zachazwa kwi- 2% ukuya kwi-10% yabathathi-nxaxheba abanyangwa nge-AmBisome:

Umzimba Uwonke

Isisu esikhulu, ii-aleji, ukosuleleka kolusu, ukwalisa oku-cell mediated immunological, ukudumba kobuso, ukuqaqanjelwa ngumzimba, intambo ebuhlungu, kunye nokungahambi kakuhle kweenkqubo.

Inkqubo Yokusebenza kweNtliziyo

Ukungabethi kakuhle kwentliziyo, ukwenyuka kwesingqi sentliziyo ngokungaqhelekanga, ukwehla kwesingqi sentliziyo, ukumelwa yintliziyo, ukwenyuka kobukhulu bentliziyo, ukopha, ukwehla koxinxelelo lwegazi kunye notshintsho kwindawo, isifo seevalvi zentliziyo (valvular), ukungasebenzi kakuhle kwemithambo, kunye nokuhamba kwegazi.

Inkqubo Yokwetyisa

Ukwehla kokulamba, ukuqunjelwa, umlomo/impumlo eyomileyo, i-asidi ephezulu, ukungalawuleki kokuphuma kwelindle, ukwenyuka kokusuza, ukopha ezimpundu, ukopha kweentsini/emlonyeni, igazi xa ugabha, ukonyuka kobukhulu besibindi, uvavanyo olubonisa okungalunganga kukusebenza kwesibindi, ukosuleleka kwenwebhu yenxenye yethumbu elikhulu (ileus mucositis), isilonda esikhulu emlonyeni kunye nokungasebeni kakuhle kwesibindi ukuya kukungavuleki kakuhle kwemithambo.

Inkqubo Yamadlala

Ukwehla kwe-hemoglobin (isakhi-bala esithwala i-oxygen kwiiseli zegazi ezibomvu), i-coagulation (amahlwili egazini), incindi eninzi, ukuqabaza ukopha, ukwenyuka kwe-prothrombin (iproteni ekhutshwa sisibindi sakho nenceda amahlwili egazini), nokwehla kubalo lwe-platelet (ii-platelets zikwanceda amahlwili egazini kwaye ukuba ngaba zehlile zinokubangela ukopha).

Ukungahambi Kakuhle Kwinguqulo Yokutya nezeSondlo

Ukwenyuka kwe-asidi emzimbeni, ukwenyuka kwe-amylase (i-amylase inceda ukwetyisa izitatshi – kwaye ukonyuka kwe-amylase amaxesha amaninzi kubonisa i-pancreatitis), i-hyperchloremia, i-hyperkalemia, i-hypermagnesemia, i-hyperphosphatemia, i-hyponatremia, i-hypophosphatemia, i-hypoproteinemia (hyper – ukwenyuka; hypo – ukwehla kwee-electrolytes ezinkulu emzimbeni nezidingeka kwimisebenzi ethile emzimbeni), ukwenyuka kwe-lactate dehydrogenase (okukwaziwa njenge-LDH – yi-enzaymi eguqula iswekile esekutyeni ukuba ibe ngamandla anokusetyenziswa ziiseli zethu, ukwenyuka kwe-nitrogen engeyoproteni (kubhekisa ngokuhlangeneyo kwizinto ezifana ne-urea, ne-ammonia), kunye ne-respiratory alkalosis ( imeko etshintsha uzinzo lwe-carbon dioxide ne-oxygen egazini.

Inkqubo Yokwakheka Komzimba

Ukuqaqamba kwamalungu, ukuqaqamba kwamathambo, ukuqina kwemisipha nokuqaqamba kwayo, kunye nomkhuhlane ogqithisileyo nengqele.

Inkqubo Yemithambo-luvo

Ukungazinzi (ukoyika okanye ixhala ), ikhoma, ukuxhuzula, ukukhohlela, ukudangala, isiyeza, ukubona izinto ngendlela engeyiyo, i-paresthesia (iimvakalelo engezizo), ukucinga okungafanelekanga nokungcangcazela.

Inkqubo Yokuphefumla

Ingxaki nokuphefumla, igazi kwizikhohlela, ukukhutywa, ukuphefumla okukhawulezayo, iimpawu ezifana nezomkhuhlane, amanzi kwimiphunga, umqala obuhlungu, i-pneumonia, ukungakwazi ukuphefumla ngokwaneleyo, ukoyiswa kukuphefumla, nokudumba kwamarhanana.

Ulusu kunye nezongezelelweyo

Ukumkelwa zinwele, ulusu olomileyo, izilonda, ukudumba kwendawo ebekutofwe kuyo, ukutshintsha kwebala lolusu, ulusu oluchachambayo, ukurhawuzelela, ukuba bomvu kolusu kunye nerhashalala enamabala amfusi.

Amalungu abalulekieleyo

Ukosuleleka emehlweni, amehlo awomileyo kunye nokopha emehlweni – ingakumbi kwimithambo yamehlo.

Inkqubo Yamalungu Okuzala

Ukungasebenzi ngokupheleleyo kwezintso, ukusilela kokusebenza kwezintso, ubuhlungu xa uchama, ukungasebenzi kwezintso, ukungasebenzi kwezintso okubangelwa yimveliso yekhemikhali okanye yebhayoloji, ukungakwazi ukubamba umchamo kunye nokopha kwilungu lobufazi.

Ingaba kuyakubakho ukungaphatheki kakuhle okubangelwa kukutsalwa kwegazi?

Le nkqubo inokubangela ubuhlungu kunye nobubomvu kwindawo ekuhlatywe kuyo umthambo okanye ekufakwe kuyo i-cannula okanye xa kukho ukuvaleka kwe-cannula. Kuya kuphela oku kancinci kancinci.

Abasetyhini Abasengafumana Abantwana

Kungakho ubungozi kusana olungekazalwa kolu lingo. Ukuba ngaba ukhulelwe okanye uye wakhulelwa ngexesha lolingo, obu bungozi bunokukuchaphazela okanye buchaphazele usana olungekazalwa. Kufanele usebenzise indlela esebenzayo yokuthintela ukukhulelwa ubuncinane iiveki ezi-4 ngaphambi kokufumana iyeza lophononongo, ngexesha lophononongo nokuya kutsho ekupheleni kotyelelelo lophononongo nakwiintsuku ezingama-30 emva kwethamo lokugqibela lophononongo.

Ngaphambi kolingo, kuya kwenziwa uvavanyo lokukhulelwa ngexesha lohluzo. Kungenzeka ukuba olu vavanyo lungaboni xa kusesezantsi ukukhulelwa kwakho. Iimvavanyo zokukhulelwa zinokuphinda zenziwe ngexesha lokuza kuqala unyango/ngaphambi kwethamo I, nangaphambi kokufumana ithamo lomjikelo ngamnye nasemva kokugqiba uphononongo. Ukuba ngaba uvavanyo lubonisa ukuba ukhulelwe uya kukhuthswa kuphononongo. Ukuba ngaba awuyivalanga inzala (ubuncinane iinyanga ezi-6 ngaphambi kokufumana iyeza lophononongo) okanye awukho kwiminyaka apho ungasayiyo exesheni (postmenopausal) (ubuncinane iinyanga ezili-12 ezilandelelanayo) kwaye ukhetha indlela yokuthintela ukukhulelwa, kufanele ukhethe iindlela ezimbini zokuvala (ikhondom yabasetyhini okanye eyamadoda kunye nokuba yi-diaphragm, okanye isiciko sesibeleko. Nceda uqaphele ukuba awunokusebenzisa ikhondom yabasetyhini kunye neyamadoda ngexesha elinye.) Ubuncinane iiveki ezi-4 ngaphambi kokufumana iyeza lophononongo, ngexesha lophononongo kunye nokuya kutsho kwiintsuku ezingama-30 emva kwethamo lokugqibela le

yeza lophononongo. Nantsi imizekelo yeendlela ezamkelekileyo zothintelo-nzala:

 Isithinteli-nzala (ukutsho oko, ikhondom yamadoda okanye yabasetyhini\*),

 I-diaphragm

 Izixhobo Ezifakwa Ngaphakathi Esibelekweni (levonorgestrel-releasing [umz. iMirena®] okanye i-copper-T [umz. iNova-T®]

 Izithinteli-nzala ezisebenza ngeehomoni, Ezizizitofu (umz. iDepo-Provera®, iNur-Isterate®), Iipilisi Eziselwayo (umz. iMinulette®, iJasmine®]

Ukuyekwa kothintelo-nzala emva kwangoku kufuneka kuxoxwe ngako kunye nogqirha ofanelekileyo. Ugqirha wophononongo uya kuxoxa nawe ngale miba ingasentla ngokuphathelele kwindlela eyiyo yokuthintela ukukhulelwa ngaphambi kokuba ungene kuphononongo.

Ukuba ngaba ungumthathi-nxaxheba oyindoda: Iqabane lakho okanye wena kufuneka nisebenzise indlela esebenzayo yokuthintela ukukhulelwa, ngexesha lophononongo nokuya kutsho kwiintsuku ezingama-30 emva kwethamo lokugqibela leyeza lophononongo.

ZEZIPHI IINZUZO EZINGAKHONA NGOKUTHATHA INXAXHEBA KOLU PHONONONGO?

Kungenzeka ukuba kubekho ukuthomalala kwiimpawu zakho Zokosuleleka loMngundo ngenxa yokuthatha kwakho inxaxheba kolu lingo. Akukho siqinisekiso sokuba iyeza olinikiweyo kolu lingo liya kuba nenzuzo ethe ngqo kuwe. Ukuba ngaba uthatha inxaxheba kolu lingo, ukuthatha kwakho inxaxheba kunokunceda abanye njengoko sithemba ukuba ulwazi olufundwe kolu phononongo lunokusetyenziswa kwixesha elizayo ukuxhamlisa abanye abantu abanesifo esifanayo.

UKUBA NGABA UYAVUMA UKUTHATHA INXAXHEBA, LUTHINI UXANDUVA LWAKHO?

Uxanduva lwakho njengomthathi-nxaxheba luquka oku kulandelayo:

• Nyaniseka malunga nembali yakho yezonyango kunye neemeko zezigulo zangoku.

• Thatha iyeza lolingo njengoko kuyalelwe ngabasebenzi bolingo.

• Xelela abasebenzi bolingo malunga nazo naziphi na iingxaki onazo ngexesha lolingo.

• Xelela abasebenzi bolingo malunga nawo onke amayeza owathathayo kuquka iivithamini, amayeza emveli nawesintu kunye nalawo athengiswa ezivenkileni, njalo njalo.

• Yazisa abasebenzi bolingo ukuba ngaba idilesi okanye inombolo yakho yomnxeba itshintshile.

• Bulumkele utywala kunye nawo nawaphi na amayeza angavunywanga ngugqirha wolingo ngelixa uthatha inxaxheba kolu lingo. Ukuba ngaba uza kuthatha naliphi na iyeza elitsha, kumele utsalele umnxeba ugqirha wolingo okanye abasebenzi bolingo ngaphambi kokuba ulithathe.

• Yazisa abasebenzi bolingo ngoko nangoko ukuba ngaba uye wakhulelwa ngelixa ukulingo.

• Ukuba ngaba ungowasetyhini kufanele usebenzise indlela yokuthintela inzala eyamkelekileyo iiveki ezi-4 ngaphambi kokufumana iyeza lophononongo nangalo lonke ixesha lophononongo kunye nokuyo kutsho kwiintsuku ezingama-30 emva kwethamo lokugqibela leyeza lophononongo.

• Ukuba ngaba uyindoda wena okanye iqabane lakho kufanele nisebenzise indlela yokuthintela inzala esebenzayo, ngalo lonke ixesha lophononongo kunye nokuyo kutsho kwiintsuku ezingama-30 emva kwethamo lokugqibela leyeza lophononongo oknye kude kufike umjikelo olandelayo we-chemotherapy.

• Yazisa abasebenzi bolingo ukuba ngaba ubukhe wakulingo lophando kwiintsuku ezingama-90 ezidlulileyo okanye ukwilingo lophando ngoku nje.

• Xelela abasebenzi bolingo ukuba ngaba unako nakuphi na ukungaphatheki kakuhle okanye ukugula ngexesha lolingo.

• Landela eminye imiyalelo (eyokutya neyamayeza okungafanele ukuba uwathathe) enikezwe ngabasebenzi bophononongo nedingekayo kuphononongo.

• Yazisa abasebenzi bolingo ngoko nangoko malunga nasiphi na isehlo esingaqhelekanga esinxulumene nonyango (ukutsho oko, isehlo esimandundu).

• Yazisa abasebenzi bolingo ngoko nangoko ukuba ngaba ulitshintshile ithamo lwawo nawaphi na amayeza angamanye.

ZEZIPHI EZINYE IINDLELA ZONYANGO EZINGEZINYE EZIKHONA ZOSULELEKO LOMNGUNDO?

Amayeza avunyiweyo efangali eyanda msinyane neyosulelayo, i-Cryptococcal Meningitis ehamba neHIV okanye kubathathi-nxaxheba abanosuleleko lomngundo ngenxa yeentlobo zosuleleko lwe-Aspergillus, iintlobo ze-Candida kunye/okanye iintlobo ze-Cryptococcus, ezikhoyo kwiindawo zentengiso. Ukuba ngaba ugqibe ekubeni ungathathi nxaxheba kolu phononongo okanye urhoxe kuphononongo, zikhona ezinye iindlela ezikhoyo. Akudingeki ukuba uthathe inxaxheba kulingo ukuze ufumane unyango. Ugqirha wakho wolingo uza kuxoxa nawe ngala mayeza angamanye. Kananjalo usengabuza ugqirha wesiqhelo wosapho lwakho ngaphambi kokuba wenze isigqibo sokuba uzibandakanye okanye ungazibandakanyi kulingo.

IINGABA KUKHO IINDLEKO EZINXULUMENE NOKUTHATHA INXAXHEBA KULINGO?

Akusayi kubakho zindleko ezizezakho ezinxulumene nokuthatha kwakho inxaxheba kolu phononongo. Akusayi kufuneka ulihlawulele naliphi na iyeza lolingo, iimvavanyo zonyango, iinkqubo okanye iimvavanyo zaselebhu ezifunekayo kolu lingo. Iintlawulo zasesibhedlele azisayi kuba luxanduva lwakho.

INGABA UNGACELWA UKUBA UPHUME KUPHONONONGO?

Ugqirha wakho wolingo, iCipla Ltd., India., (aBaxhasi bolu lingo), Amagunya Aselulawulweni kunye neKomiti Ezimeleyo Yokuziphatha Ngokusesikweni / iKomiti yeZiko Yokuziphatha Ngokusesikweni / iBhodi yoQwalaselo yeZiko (IEC /IRB) zinelungelo lokuyekisa ukuthabatha kwakho inxaxheba kulingo ngalo nangaliphi na ixesha. Ungakhutshwa kulingo ngaphambi kwexesha ngaphandle kokuvuma kwakho ngenxa yaso nasiphi na isizathu kwezi zilandelayo:

• Ukuhlala kwakho kulingo kubeka impilo yakho ebungozini.

• Kwimeko yeSehlo Esimandundu, edinga ukuba uyeke ngokusisigxina ukufumana iyeza lophononongo.

• Udinga unyango olungavumelekanga kolu lingo.

• Kufunyaniswe ukuba ungenele uphononongo ngokophula le protokholi.

• Awuyilandeli imiyalelo yolingo.

• Uye wakhulelwa (kubathathi-nxaxheba basetyhini) ngexesha lolingo.

• Ugqirha woLingo ubona ukuba akukulungelanga ukuqhubeka ukulingo.

• Ukuba ngaba luyekisiwe ulingo.

• Ukuba ngaba udinga ithamo eliphezulu okanye ukutshintshwa kwethamo leGlucocorticoids ngexesha lophononongo.

• Ezinye izizathu ezamkelekileyo nezingachazwanga kolu xwebhu

• Ukuba ngaba ixesha lokufakwa kwamayeza ophononongo emithanjeni alikho kwixesha elimiselweyo lweeyure ezi-2 (+ 05 imizuzu), umphandi ke ngoko angakukhupha kuphononongo.

UYA KWAZISWA, UKUBA NGABA KUKHO NALUPHI NA ULWAZI OLUTSHA OLUYE LWAFUMANEKA NOLUNOKUCHAPHAZELA ISIGQIBO SAKHO SOKUTHATHA INXAXHEBA KULINGO

Ulwazi olukule fomu luchaza oko kwaziwayo malunga nolingo lophando ngexesha isayinwa ngalo. Ukuba ngaba kuye kwafunyaniswa naluphi na ulwazi olutsha ngexesha lolingo lophando nolunokuthi luchaphazele izizathu sakho sokuba uqhubeke okanye ungaqhubeki nokuthatha inxaxheba kulingo, uya kwaziswa malunga nolwazi olo ngexesha elifanelekileyo.

AMALUNGELO NEEMBUYEKEZO ZAKHO

Ukuthatha kwakho inxaxheba kolu lingo kokokuzithandela kwaye ungarhoxa kuphononongo ngalo nangaliphi na ixesha ngaphandle kokuba kufuneke unike izizathu zokwenza oko kwaye ukwala ukuthatha inxaxheba akuyi kuba naso nasiphi na isohlwayo okanye ukulahlekelwa ziinzuzo eselungelweni lokuba uzifumane xa bekungenjalo. Ukuba ngaba ngalo naliphi na ixesha uziva uphatheke kakubi okanye ugula siso nasiphi na esinye isigulo, nceda uxelele ugqirha wakho wolingo okunakekelayo. Ukuba ngaba unyango lukhangeleka lungakulungelanga luya kuyekiswa. Kungenzeka ukuba uphononongo luyekiswe ngaphandle kwemvume yakho. Umphandi uya kukuxelela ukuba ngaba kukho naluphi na ulwazi olutsha oluthe lwavela ngexesha lophononongo nolunokuthi luchaphazele ukufuna kwakho ukuqhubeka kuphononongo.

Akuyi kuhlawulwa ngokuthatha inxaxheba kolu phando lophononongo. Uza kufumana imbuyekezo ngokunxulumene nazo naziphi na iindleko “eziphume epokothweni” ezifana neendleko zokuhamba kwakunye nezexesha olichithileyo nokuphazamiseka, kwaye uya kufumana imali ebubuncinane obungama-R250 ngotyelelo lophononongo ngalunye. Kumatyelelo ophononongo amaninzi uyakube usesibhedlele /ekliniki ukwenzela zonke iinkqubo ezinxulumene nophononongo neziya kuhlawulelwa kunye nazo zonke izidlo njalo njalo, ezinikezwayo. Iindleko ezongezelelweyo ezivela kwiinkqubo ezingeyomfuneko kolu phononongo aziyi kuhlawulwa nguMxhasi okanye umncedisi womxhasi.

Nayiphi na imbuyekezo ehlawulelwa nakuphi na ukwenzakala okubangwe kukuthabatha inxaxheba kwakho kolu phononongo iya kungqinelana nezikhokelo zasekhaya. Umxhasi uya kuhlawulela iindleko zonyango lwamayeza ngako nakuphi na ukwenzakala okungenxa yonyango ngqo ngeyeza lophononongo okanye inkqubo yophononongo (esetyenzisiweyo njengoko kuchaziwe kwiprotokoli yophononongo). Umxhasi uya kukubuyekeza apho kubekho khona ukwenzakala ngenxa yenkqubo eyenziweyo engangqinelaniyo neprotokoli yophononongo okanye apho oogqirha bophononongo baye benza ngokungakhathali.

Umxhasi uthathe ipolisi ye-inshorensi yokuhlawulela imbuyekezo yako nakuphi na ukwenzakala komntu okubangelwe kukuthatha iyeza lophononongo kwakho, ngaphandle kokuba ukwenzakala okunjalo komntu akukho ngenxa yesiphosiso okanye ukungakhathali kukagqirha wophononongo okanye iqela lakhe.

Umxhasi uthathe i-inshorensi Allianz GCS enenombolo yepolisi engu- ZAL000238150 ukwenzela imeko yokwenzakala okunxulumene nolingo lonyango yaye uyavuma ukukubuyekeza ngokohlobo lokwenzakala kwakho, ngokobukhulu nokuzingisa kokwenzakala ngokuhambelana neZikhokelo zeShishini loMbutho woXubo-Mayeza waseBrithani (Association of the British Pharmaceutical Industry Guidelines) (ABPI) kwimeko yokwenzakala okanye isiphumo ebesingalindelekanga esibangelwa ngqo kukuthatha kwakho inxaxheba kulingo.

Ngokwezikhokelo ze-ABPI umxhasi wophononongo kufuneka akubuyekeze, ngaphandle kokuba wena unike ubungqina bokuba nguye owenze impazamo, nangawuphi na umonzakalo owenziwe kukunikwa iyeza lophononongo okanye zezinye iinkqubo ezenziweyo neprothokholi yolu phononongo.

Umxhasi akayi kuba nembopheleleko ngayo nayiphi na ilahleko, ukwenzakala kunye/okanye umonakalo onokuwufumana ukuba loo lahleko ibangelwe:

Kukusebenzisa naliphi na elinye iyeza ngelixa lophononongo

Nakuphi na ukwenzakala okubangelwe kukuba ungalandelanga imiqathango nemithetho yokuziphatha okanye nayiphi na imiyalelo okanye ulwalathiso onokulunikwa ngugqirha wophononongo

Nakuphi na ukwenzakala okubangelwa siso nasiphi isenzo okanye ukungenzi nantoni na obumele uyenze ukuhlangabezana kakuhle neziphumo ebezingalindelekanga okanye ukwaliwa liyeza lophononongo

Nakuphi na ukwenzakala okwenzeke ngenxa yokungakhathali kwicala lakho

Ngokusayina le Fomu yeMvume Esekelwe kuLwazi, awunikezeli nangawo nawaphi na amalungelo akho asemthethweni. Ngokukodwa, ilungelo lakho ngokusemthethweni lokufaka ibango lembuyekezo yokwenzakala apho unokunika ubungqina bokungakhathali alichaphazeleki.

Ukuba ngaba une-inshorensi yezonyango nceda ukhangele kwinkampani yakho ye-inshorensi ukuba ukuthabatha kwakho inxaxheba kolu phononongo akuyi kuchaphazela ipolisi yakho na.

UBUMFIHLO BABATHATHI-NXAXHEBA

Ubumfihlo bakho buza kuhlonitshwa. Ulwazi olwenza ukuba ukwazi ukwaziwa alusayi kukhutshwa ngaphandle kwemvume yakho ngaphandle kokuba oko kudingeka ngokwasemthethweni okanye yimimiselo. Ngugqirha wolingo kuphela, iqela lophononongo, iCipla Ltd., India (umxhasi wolingo), kunye nabameli bakhe abagunyazisiweyo, amaqumrhu karhulumente kumanye amazwe apho iyeza lophononongo linokuqwalaselwa ukuze lamkelwe, Amagunya oLawulo kunye neKomiti Yokuziphatha Ngokusesikweni/iBhodi yoQwalaselo yeZiko abaya kukwazi ukufikelela kwiinkcukacha eziyimfihlo nezikwazisa ngoonobumba bamagama akho/inombolo yomthathi-nxaxheba yophononongo. Ngenxa yemfuneko yokuba la maqumrhu akwazi ukufikelela kolu lwazi, ubumfihlo obugqibeleleyo abunakuqinisekiswa.

Uya kwaziswa ngoonobumba bamagama akho kunye nenombolo yomthathi-nxaxheba yophononongo kuphela. Awusayi kwaziswa kuzo naziphi na iingxelo okanye amaxwebhu apapashiweyo eziziziphumo zolu phononongo.

UQHAGAMSHELWANO NABA BALANDELAYO XA NGABA UNAYO NAYIPHI NA IMIBUZO MALUNGA NOPHONONONGO NGEXESHA LOKUTHATHA KWAKHO INXAXHEBA

Olu phononongo luvunywe liBhunga loLawulo lwaMayeza (Medicines Control Council (MCC)) neKomiti Yokuziphatha Ngokusesikweni Yamayeza. Ngaphezulu, uphononongo luza kuqhutywa ngokwesibhengezo saseHelsinki (inguqulelo yama-2013) neziKhokelo zoKwenziwa kweMisebenzi ngeNdlela eFanelekileyo ekuQhutyweni koLingo loNyango kubaThathi-nxaxheba abangaBantu eMzantsi Afrika, Uhlelo lwesi-2 lwama-2006, olujongene namalungelo akho njengomthathi-nxaxheba kuphando nolukhokela ugqirha wophando (umphandi) kuphando lwezonyango olunabathathi-nxaxheba abangabantu

Ungabuza imibuzo malunga nale fomu okanye ulingo ngalo nangaliphi na ixesha. Usenokuba nemibuzo malunga nolingo lophando, umonzakalo onxulumene nophando okanye intlawulo ngexesha lolingo. Unokuba nemibuzo engeminye. Kufanele uqhagamshelane nogqirha wolingo okanye abasebenzi bolingo ngayo nayiphi na imibuzo okanye izinto ezikuxhalabisayo ezinxulumene nophononongo.

Igama loMphandi oyiNtloko: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Idilesi yeZiko: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Inombolo Yoqhagamshelwano: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I-imeyile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Malunga nolwazi olunxulumene nophando ngokubanzi, amalungelo akho njengoMthathi-nxaxheba wolingo, kunye/okanye umonzakalo onxulumene nolingo, ungaqhagamshelana nosihlalo wekomiti Yokuziphatha Ngokusesikweni Yamayeza.

Igama likaSihlalo: Gqr CSJ Duvenage

Idilesi yeKomiti Yokuziphatha Ngokusesikweni: 123 Amcor Road, Lyttleton Manor, 0157

Inombolo Yoqhagamshelwano: Umnxeba:012 664 8690 Ifeksi: 012 664 7860

I-imeyile: marzelle@pharma-ethics.co.za

Ukuba unayo nayiphi na imibuzo malunga nolu lingo, kufuneka okokuqala uyixoxe nogqirha wophononongo okanye le komiti yokuziphatha echazwe apha ngasentla. Ukuba awuzifumani iimpendulo ezikonelisayo, kufuneka ubhalele kwi-MCC ku:

The Registrar

Medicines Control Council

Department of Health

Private Bag X828

Pretoria, 0001

Ifeksi: (012) 395 8032

I-imeyile: gouwsj@health.gov.za

Ifomu yeMvume Esekelwe Elwazini

Inombolo yoPhononongo: IPD/CLI/15/003

Isihloko soPhononongo

Amaziko onyango awohlukeneyo, olwenziwa kumaziko awohlukeneyo, olungafihlwanga, olunamaqela akhiwa ngendlela engahlelwanga, olunamathamo awohlukeneyo, iindlela zonyango ezimbini, amaxesha amabini okudlulela kwelinye, oluthelekisa ukufana kweyeza eliyimveliso eVavanywayo [i-Amphotericin B (i-Liposome esetyenziswa kwisitofu) i-50 mg/vial, Cipla Ltd., India] kunye nemveliso eyiReferensi [i-AmBisome® (i-Amphotericin B) i-Liposome esetyenziswa kwisitofu eyi-50 mg/vial), Gilead life sciences, USA] kwizigulana ezingabantu abadala abanosuleleko lomngundo.

Inombolo yohluzo yomthathi-nxaxheba.:\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Umthathi-nxaxheba: Nceda ubhale usayino olufutshane okanye ushicilelo lukabhontshi apha ngezantsi. Kuthetha ukuba ulufumene olu lwazi, uyibuzile imibuzo onayo ngoku malunga nophando kwaye lo mibuzo iphendulwe.

Inobolo ye-Sr. Iziqinisekiso Utyikityo loMthathi-nxaxheba / Ushicilelo lukabhontsi

(i) Ndiyaqinisekisa ukuba ndilifundile kwaye ndiyaliqonda eli phepha lolwazi uhlelo 01, lomhla 16th Julayi 2015 lolu phononongo lungasentla kwaye ndilifumene ithuba lokubuza imibuzo.

(ii) Ndiyaqonda ukuba uthabatho nxaxheba lwam kukuzithandela kwaye ndikhululekile ukuba ndingarhoxa ngalo naliphi na ixesha, ngaphandle kokunika nasiphi isizathu, nangaphandle kokuba ukhathalelo lwam lwezonyango okanye amalungelo omthetho achaphazeleke.

(ii) Ndiyaqonda ukuba kuza kwenziwa uvavanyo lwe-HIV kwiisampuli zencindi yegazi. Iziphumo zovavanyo ziya kugcinwa ziyimfihlo kuze kwabelwano ngazo kuphela ukwenzela izizathu ezibalulekileyo.

(iv) Ndiyaqonda ukuba uMxhasi (i-Cipla Ltd., India) wolingo lonyango, abanye abasebenza egameni loMxhasi, iKomiti Yokuziphatha Ngokusesikweni kunye namagunya olawulo abasayi kudinga mvume yam ukuze bajonge iirekhodi zam zempilo ngokunxulumene nolu phononongo lwangoku kunye nalo naluphi na uphando lwexesha elizayo olunokuthi luqhutywe ngokunxulumene nalo, nokuba ngaba ndirhoxile kulingo. Ndiyaluvuma olu fikeleko. Kodwa ke, ndiyaqonda ukuba izazisi zam azisayi kuvezwa kulo naluphi na ulwazi olukhutshelwe amaqela angamanye okanye olupapashiweyo.

(v) Ndiyavuma ukuba ndingabambi ukusetyenziswa kwazo naziphi na iinkcukacha okanye iziphumo ezivele kolu phononongo ngaphandle kokuba oko kusetyenziswa kokweenjongo zezenzululwazi kuphela.

(vi) Ndiyavuma ukuthabatha inxaxheba kuphononongo.

(vii) Ndiyavuma ukuthobela imiyalelo kagqirha wolingo kwanokwazisa abasebenzi bolingo ngoko nangoko ukuba ngaba kuye kwavela naziphi na iingxaki ngexesha lophononongo.

(viii) Ndiyazi, ukuba kufanele ndifumane ikopi esayiniweyo yolu xwebhu.

(ix) Ndiyavuma ukuthatha inxaxheba kuhlolo lwe- pharmacokinetic ngokuzithandela.

X Ndiyavuma ukuba iisampuli zam ziya kuhanjiswa ngeenqanawe ukusiya kwilebhu ekhuselekileyo engaphandle kwaseMzantsi Afrika (ukuba kufanelekile)

\* Nceda uqinisekise ukuba ugqirha wakho wophononongo ukunika ikopi esayiniweyo yefomu nebhalwe umhla emva kwamaxwebhu azeleyo.

Umthathi-nxaxheba: Ngokusayina le fomu yemvume, uchaza ukuba ukhetha ngokuzithandela ukuthatha inxaxheba kolu phando.

Igama loMthathi-nxaxheba Utyikityo/Ushicilelo lukabhontsi Umhla

(Kudingeka ukusayina kwengqina elingakhethiyo xa umthathi-nxaxheba engakwazi ukufunda nokubhala.)

Ingqina Elingakhethiyo: Kudingeka ingqina xa ngaba uMthathi-nxaxheba engakwazi ukufunda uxwebhu lwemvume.

Igama leNgqina Elingakhethiyo Utyikityo

Umhla

Ukuzazisa neenkcukacha zoqhagamshelwano:

Qaphela:

Ngokusayina, iNgqina Elingakhethiyo lingqina ukuba ulwazi olukwifomu yemvume kwakunye naluphi na olunye ulwazi olubhaliweyo luchazwe ngendlela echanekileyo, kwaye kubonakala ukuba luqondiwe nguMthathi-nxaxheba. Iikopi zephepha lolwazi lomthathi-nxaxheba kunye nefomu yemvume esekelwe elwazini nesayinwe ngokukuko ziza kudluliselwa kumthathi-nxaxheba okanye umntu ommeleyo.

Umntu oqhuba ingxoxo yemvume esekelwe elwazini ukuba ngaba ayinguye umphandi: Ukusayina kwakho apha ngezantsi kuchaza ukuba uluchazile uphando kuMthathi-nxaxheba / ummeli woMthathi-nxaxheba kwaye uyiphendule nayiphi na imibuzo anayo malunga nophando.

Igama loMntu oqhuba inkqubo yokufunyanwa kwemvume ukuba ngaba ayinguye umphandi Utyikityo

Umhla

(Ngumntu wezonyango onegunya wolu phando kuphela onokuchaza uphando aze afumane nemvume esekelwe elwazini.)

Umphandi:

Igama loMphandi Utyikityo

Umhla

(Ngumntu wezonyango onegunya wolu phando kuphela onokuchaza uphando aze afumane nemvume esekelwe elwazini.)

Ndiyavuma ukuba ndiyifumene ikopi esayiniweyo ye-PIS ne-ICF

Utyikityo /Ushicilelo Lukabhontsi woMthathi-nxaxheba:

Umhla: